

Thesis Approval Form

AMERICAN DIABETIC ASSOCIATION STANDARDS IN AN AIR FORCE MEDICAL CLINIC

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ABSTRACT

One in ten of the population over the age of 65 has been diagnosed with diabetes mellitus, Type II diabetes accounting for 90% of these cases. Diabetes, the seventh leading cause of visits to primary care physicians, requires continuing medical care and patient education. Long term management presents a challenge to the military health care system faced with frequent provider turnovers. Standards of care not only define quality of care but provide a means to decrease the threat on comprehensive care associated with these turnovers. This descriptive quantitative study measured adherence to ten American Diabetic Association Standards of Medical Care in a military medical clinic utilizing the Diabetes Quality Assurance Checklist. Ratings of good to excellent were obtained in 43 percent of the medical records. The DQA Checklist went beyond these recommended ADA Standards to include important elements of care not routinely included in the continuing diabetic treatment regimen. Ten percent of the records obtained ratings of good to excellent in overall adherence to elements of continuing diabetic care listed on the DQA Checklist.

AMERICAN DIABETIC ASSOCIATION STANDARDS IN AN AIR FORCE
MEDICAL CLINIC

By

DEBORAH KAY FLAGG

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DEDICATION

I would like to dedicate this thesis to my husband, Ed, and my children, Sarah, Molly, and Sheldon, whose many sacrifices made the completion of this thesis a reality. Hugs and kisses, Mom.

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CHAPTER ONE

Introduction

Approximately 11% of the US population is over age 65 and by the year 2020 it is estimated that this percentage will increase to 17% (Meyers, 1991). Of this elderly population, currently 1 in 10 has been diagnosed with diabetes and Type II diabetes accounts for approximately 90% of diabetic patients (American Diabetic Association, 1988). Type II diabetes has a nationwide prevalence of 2.78% (Kerr, 1995) and this prevalence increases with age. Utilizing the Bureau of Census population projections for 1987, Helm (1992) projected that the number of diabetic patients 65 years and older will grow at an average of 1.7% per year between now and the year 2015, adding an average of 55,000 new patients per year to this age group. During the next 20 years, this number is expected to increase to approximately 120,000 patients per year reaching a total of seven million diabetics age 65 or older in the year 2035.

Diabetes is the seventh leading cause of visits to a primary care physician in the general population (Kerr, 1995). It is an important cause of nontraumatic lower-extremity amputations, end-stage renal disease, blindness among working-age adults, disability, premature mortality, and health-care costs; and an important risk factor for the development of other chronic conditions such as ischemic heart disease and stroke (US Department of Health and Human Services, 1993). Diabetes was the underlying cause of death for 48,259 people in 1992 and a contributory cause of death for approximately 118,678 people (ADA, 1993a). It is a costly disease, not only in the number of human lives, but also in dollars and cents. The total annual cost of diabetes in 1987 was estimated at \$20.4

billion dollars. In 1992 the estimated total economic cost of diabetes was \$91.8 billion dollars (\$45.2 billion dollars in direct costs and \$46.6 billion dollars in productivity losses).

The growing number of elderly and specifically the diabetic elderly is of concern to all primary care providers. When data from the National Ambulatory Medical Care Survey conducted from March 1985 to February 1986 was extrapolated to all office-based-physicians in 1985, it was estimated that 21.3 million visits involving diabetes were made to office-based physicians. This proportion increased with age from 3.3% to 7-8% for patients 55 to 84 years old (Harris, 1990a). Over 78% of these visits for diabetes were made to primary care physicians with Internal Medicine tallying 33.2%, General Practice 21.7% and Family Practice 20.6%. This is important to Nurse Practitioners (NPs) because, typically, many NPs work in ambulatory, primary care settings and have been found to provide as much as 90% of the primary health care services physicians can provide. Advanced Practice Nurses are providing the same diagnostic and management services that most primary care physicians are providing, and refer to physicians when the client problems are outside of the nurses' scope of practice (Pepperdine & Taylor, 1993). These services would include healthcare management of the diabetic patient, particularly the stable non-insulin dependent (Type II) diabetic.

Nurse Practitioners can be found in the military as well as the civilian healthcare arena primarily as Pediatric, OB-Gyn, and Mid-Wife NPs. In fact, the Air Force Nurse Corps is opening its doors to Family Nurse Practitioners in 1996. The Military Health Services System, comprised of 148 hospitals and over 800 medical and dental clinics, is one branch of the healthcare system that provides care for a specific portion of the elderly

population, namely military retirees and their spouses (Lanier & Boone, 1993). An example of heavy usage of the military clinics can be found in the quarterly report dated December 31, 1994, in which the Department of Defense reported a total of 970,169 surgical outpatient visits in the US fixed military medical facilities by retired uniformed personnel and 1,235,770 surgical outpatient visits by dependents of retired and deceased US uniformed personnel (Washington Headquarters Services, 1994). Outpatient clinics in the Military Health Services System are not currently required to maintain statistics on patients with diabetes mellitus. However, considering the prevalence and predicted growth of diabetes in the general population over the age of 65, it is easily assumed that diabetes is also a prevalent problem in the elderly population seen in the military healthcare system.

Diabetes is a chronic illness “which requires continuing medical care and education to prevent acute complications and reduce the risk of long-term complications” (ADA, 1994, p. 616). Medical management of diabetes requires that certain assessments be accomplished with each visit or within specified general time frames. This long term medical management of diabetes presents challenging problems to military clinics where changes in patient population, medical officer personnel and clinic staffing are frequent (Graber, Cerchio, & Herl, 1968). The frequent turnover of military healthcare providers presents a potential threat to the comprehensive care provided to their diabetic patients. These turnovers are due to such things as manning assistance; temporary duty assignments for education, humanitarian causes, or military conflicts; permanent change of duty assignment to another duty location; and retirement or discharge from the service. Although individual assignments vary, the average length of stay of a provider at an Air

Force or Army establishment is three to four years. However, this assignment may be interrupted at any time in order to meet administrative and operational taskings that the service deems necessary. The length of the interruption varies with the task assignment.

One effective means to assure that the medical care provided is fulfilling the requirements of good diabetic management is through the use of standards of care such as those published by the American Diabetes Association. These standards of care not only define the quality of care, but they also provide the military outpatient clinics with a means to decrease the threat on continuity and coordination of care associated with frequent provider turnover.

In its attempts to improve cost effectiveness and access to health care, the Department of Defense is implementing a managed care program entitled TRICARE for all military services. Activation of this health maintenance program will be completed in 1997. Colonel Karen Wiess, Consultant for Internal Medicine for the Air Force Surgeon General, (personal communication, 1995) stated that utilizing monitoring techniques such as adherence to standards of care will be essential not only in assessing cost effectiveness but evaluating the quality of care provided.

Research Question

If the assumption is made that medical care providers do follow some type of diabetic standards in their practice, how closely do they follow these standards and how effective are they in maintaining comprehensive care in the military healthcare system? This research study addressed the first question: to what extent do healthcare providers managing Type II diabetes mellitus in military outpatient clinics meet the standards of care established by the American Diabetes Association?

Conceptual Framework

There are two components in the practice style of practitioners: technical and interpersonal. Interpersonal style includes many aspects of the way clinicians relate to their patients (Tarlov et al., 1989). Technical style of care refers to the specific services used (the knowledge and judgment used in arriving at the appropriate strategies of care) and on the skill in managing episodes of treatment. The goodness of this technical performance is compared with the best in practice which is believed to produce the greatest improvement in health. The quality of technical care is proportional to its expected ability to achieve those improvements made possible by healthcare science and technology or its effectiveness. Judgments on this technical quality rely on the best in current knowledge and technology (Donabedian, 1988).

A standard is a measuring scale by which the quality of practice, service, or education can be judged (Aiken & Catalano, 1994). Its purpose is “to provide guidelines and to define appropriate levels of quality patient care that must be implemented to protect the patient” (p. 58). A standard can represent the average degree of skill, care, and diligence exercised by members of the same profession under the same or similar circumstances or standards can be set very high and represent the best medical care that can be provided (Donabedian, 1966).

Donabedian described two sources from which quality standards can be derived: empirical and normative. Empirical standards stem from specific examples of actual practice. They are used to compare medical care in one practice setting with another or with averages and ranges obtained from similar settings. An example is the prescription

patterns in a medical care clinic used as a standard to evaluate private practice. Normative standards derive from legitimate knowledge and values rather than from specific examples of actual practice. Their validity relies on the agreement of these facts and values within the profession. Sources of this knowledge include professional associations, accreditation bodies, state and federal legislatures, and healthcare facilities (Aiken & Catalano, 1994). Standards of care can be set by “standard textbooks or publications, panels of physicians, highly qualified practitioners who serve as judges, or a research staff in consultation with qualified practitioners” (Donabedian, 1966, p. 177). Standards of care vary according to the level of care being measured and their generality or specificity. Those that evaluate a particular clinical aspect of patient care and have significance for a smaller segment of practitioners are referred to as profession specific. Standards also vary according to the type of care involved and who is delivering the care (Aiken & Catalano, 1994).

Although standards of care can be based on a local or national standard, with increased specialization, many courts are holding healthcare practitioners to a national standard of care. The assumption is that standards of care, local or national, will be followed because “standards may be used for evidentiary purposes to determine whether the standard of care has been violated in any given case” (p. 71).

There are three basic variables of care (structure, process, and outcome) which can be evaluated against these standards that define the quality of care. Structure denotes the attributes of the settings in which care occurs; process denotes what is actually done in giving and receiving care (to include patient and provider activities); and outcome denotes the effects of care on the health status of patients and populations (Donabedian, 1988).

Good structure increases the likelihood of good process, and good process increases the likelihood of a good outcome. “There must be preexisting knowledge of the linkage between structure and process, and between process and outcome, before quality assessment can be undertaken” (p. 1745).

What little is known about the relationship between structure and process or structure and outcome comes from organizational sciences which are relatively young. This results in a scarcity of knowledge which does not allow the assertion that care has been good or bad.

Knowledge about the relationship between technical process of care and outcome derives from the healthcare sciences. Assessments of the quality of the technical process of care varies in certainty and persuasiveness and are dependent upon strengths and weaknesses of our clinical science. If we are certain that a strategy of care produces the best outcome for our patients, we are then confident that its practice represents the highest quality of care. If we are unsure of the relationship, then our assessment of quality is also less than certain. Because a multitude of factors influence outcome, it is not possible to know for certain the extent to which an observed outcome is the result of a process of care. Therefore, direct assessment of the process is needed for confirmation.

Assessment of the process of care is justified by the assumption that there is an interest in whether what is now known to be “good” medical care has been applied. Judgments are based on such things as appropriateness, completeness and redundancy of information obtained from the history, physical and laboratory tests; technical competence; evidence of preventive management; coordination and continuity of care (Donabedian, 1966).

In 1989 the American Diabetes Association published Standards of Medical Care for Patients with Diabetes Mellitus which defined the minimum medical care for people with diabetes. Following the publication of the Diabetes Control and Complications Trial in 1993, the ADA revised its standards to reflect the results of this study which confirmed that strict control of blood glucose can prevent or dramatically reduce complications of diabetes (Deeb & Skyler, 1994). The ADA states that the standards of care will provide diabetic healthcare providers with a means to set treatment goals, assess the quality of diabetes treatment, identify areas where more attention or self-management training is needed, and define timely and necessary referral patterns to appropriate specialists (ADA, 1995). Position statements, such as the ADA standards, have been evaluated by representatives of ADA Professional Section Councils and outside experts, reviewed and approved by the Professional Practice Committee and the Executive Committee of the Board of Directors. The ADA also provides the diabetic patient with a handout entitled “Standards of Care: But what is good care?” which explains that these standards are guidelines that give doctors the most up-to-date information on diabetic care and are a means for the patient to know what to expect from the provider and to check whether the provider is doing a good job. The 1994 standards outline the components of the medical history, physical examination, and laboratory evaluations necessary for the initial patient visit and the management plan that should be formulated. The standards also provide guidance for continuing care to include recommendations on medical history, office visit frequency, examination components, and laboratory evaluations. They address the special requirements for the care of children and adolescents, pregnant women, patients with concomitant disease, and the needs for early diagnosis and treatment of such problems as

retinopathy, hypertension, neuropathy, cardiovascular disease, dyslipidemia, nephropathy, and foot care (ADA, 1994). (See Appendix A.)

Ideally standards and criteria are derived from scientifically founded knowledge. If not, then they are usually developed by a panel of experts representing the best most informed authoritative opinion on the subject. Explicit criteria, highly structured, specific, written, requiring little to no individual judgment by the evaluator, help maintain consistency and objectivity in assessing process (Donabedian, 1988; Council on Medical Service, 1986).

Wylie-Rosett, Cypress, and Basch (1992) developed a Diabetes Quality Assurance Checklist to measure adherence to the ADA medical standards for diabetes. (See Appendix B.) Wylie-Rosett et al. listed four benefits of their checklist. Health professionals with limited experience in diabetes management could use the checklist to review charts with minimal training. Reviewing diabetes care with the checklist could assist in describing continuing care of patients with diabetes, identifying specific problems in ambulatory settings, and setting goals for intervention programs to improve patient care. It could assist in training healthcare providers how to achieve and document care consistently with minimal medical standards for continuing care of diabetes.

The key source of information when assessing the process of care and its immediate outcome is the medical record, a business and legal document servicing not only providers, but also third-party payors, lawyers, and clinical investigators (Romm & Putnam, 1981). The medical record outlines the clinical course of an illness, identifying “the patient’s status in order to document the need for care and to plan, deliver, and evaluate that care” (Aiken & Catalano, 1994, p. 236). It can provide evidence of quality care, evi-

dence of the legal responsibilities to the patient, evidence of standards, rules, regulations, and laws regarding the professional practice, documentation of professional and ethical conduct and responsibility, data for planning future healthcare, and data for quality-of-care review (1994).

Definitions and Variables

Healthcare Providers.

All active duty physicians, nurse practitioners, and physician assistants

Type II Diabetes Mellitus.

A class of diabetes mellitus characterized by chronic hyperglycemia and disturbances of carbohydrate, fat, and protein metabolism; usually not insulin-dependent or ketosis prone; generally occurring after age 40; with obesity a frequent precipitating factor (McCance & Huether, 1994)

Management of Type II Diabetic Patients.

Includes incorporating the patient and family into the healthcare team, obtaining/updating patient history, performing physical assessments, evaluating the patient's current status and goal attainment, initiating treatment changes, making referrals, coordinating with other members of the healthcare team and ancillary healthcare members, educating the patient and family, and providing them with emotional support

Standard.

That which is established by custom, or authority as a model, criterion, or rule for comparison of measurement (Thomas, 1985, p. 1616). In this study the management of diabetic care, relative to the 1994 ADA Standards, is measured by the scores obtained on the Diabetic Assessment Quality Checklist. (See Appendix B).

American Diabetic Association (ADA).

A nonprofit health organization with more than one million volunteers including over 10,000 physicians, scientists, nurses, dietitians, pharmacists, social workers, and educators dedicated to the prevention and cure of diabetes. The ADA funds research (with a 90 million dollar investment in diabetes research to date), publishes scientific findings, and provides education to diabetics and their families, health professionals, and the public (ADA, 1993b).

Variables are the military healthcare providers and the American Diabetes Association Standards of Medical Care.

Limitations

Medical actions not accomplished during the designated time frame may be a result of patient noncompliance rather than omission by the provider. However, this should be documented in the record.

No statistics are available on the number of diabetic patients receiving outpatient care in the military healthcare system.

There is no guarantee that all of the providers present during the selected time frame will be represented in the sample. Nor do the results necessarily represent the adherence of the current staff at the clinic.

The medical record is often incomplete in what it documents, frequently omitting significant elements of technical care. Information recorded may be inaccurate because of errors in diagnostic testing, in clinical observation, in recording, and in coding. The concern arises whether assessing the quality of care based on the medical record is rating the record or the care provided. A given set of records may cover a limited segment of care

providing no information about what comes before or after (e.g. in the hospital). Accurate, complete assessment of quality of care depends upon appropriate and accurate recording with collation of records from various sites. (Wylie-Rosett et al., 1992).

The study was restricted to one clinic in one medical care setting.

The review of medical records was limited to 30 charts.

CHAPTER TWO

Literature Review

Diabetes mellitus is a chronic disease characterized by abnormal glucose utilization through relative or absolute deficiency of insulin secretion resulting in the elevation of blood glucose concentrations (Fain, 1993; Gregerman, 1995).

Diabetes has a prevalence of almost seven million and an incidence of 650,000 to 750,000 new cases per year. It is estimated that another seven million cases of diabetes are undiagnosed making the total number of diabetics nearly 14 million. (Fain, 1993; Deeb & Skyler, 1994). Harris reported that “the population of diabetes among people 65 years and older is expected to reach 3.9 million in the year 2020, a 44% increase over the 2.7 million estimated from 1986 to 1988” (Harris, 1990b, p. 707).

Type II or non-insulin-dependent diabetes accounts for 80 to 90% of the patients with abnormal glucose metabolism (Gregerman, 1995). The principal characteristics of Type II diabetes include “onset in middle-aged and elderly patients, absence of ketoacidosis, and control of blood sugar levels with carbohydrate restriction, weight reduction, and use of oral hypoglycemics”, with obesity and family history as the most important risk factors (Fain, 1993, p. 2).

Diabetes is a very complex disease affecting “virtually every tissue and organ in the body causing degeneration and destruction of the blood vessels, the nervous system (neuropathy), structural and supporting tissues of the eye (retinopathy), and kidney (nephropathy)” (p. 1). Hypertension accelerates diabetic retinopathy and diabetic renal disease and is a major risk factor for coronary atherosclerosis (Gregerman, 1995). Other

major risk factors for microvascular and macrovascular complications are hyperlipidemia, hyperglycemia, lack of exercise, and smoking (ADA, 1988).

In 1988 the US Department of Health and Human Services (1993) reported 40,368 deaths in which diabetes was listed as the underlying cause and 157,265 deaths in which the number of deaths were diabetes-related. Today diabetes is the seventh leading cause of death by disease in the US today with approximately 150,000 deaths from diabetes and its complications (Fain, 1993).

Most of the deaths caused by diabetes are due to complications such as atherosclerosis and chronic renal failure. In 1988 more than half of the diabetes-related deaths had major cardiovascular disease listed as the underlying cause (N=80,876). Of these deaths, 61% were attributed to ischemic heart disease and 14% to stroke (USDHHS, 1993). Gregerman (1995) reported a three-fold increase in the risk of atherosclerotic heart disease and atherosclerotic peripheral vascular disease in patients with diabetes.

Diabetic retinopathy, one of the leading causes of blindness in the US, can cause a visual loss that is potentially more severe than blindness due to other causes (Gregerman, 1995). However, it does not cause visual symptoms until it is fairly advanced.

Progressive renal disease is a life-threatening complication of diabetes. The age-standardized incidence of end-stage renal disease-DM increased more than five-fold from 38.4 per 100,000 in 1980 to 201.9 per 100,000 in 1989. The ADA (1988) reported an incidence of 5 to 10 percent in diabetic renal disease 20 years after diagnosis in patients whose diabetes was diagnosed after age 30.

In 1988, 55,000 of the hospital discharges with lower extremity amputations were reported among persons with diabetes representing about half of all discharges with lower extremity amputations.

In 1988, 3.3 million diabetics, approximately half of all known diabetics, reported a limitation in activity. This was an increase from 3.1 million in 1983.

“Diabetes and its complications shorten life-span, limit normal daily activities, create disability, increase use of healthcare services, and impose economic burden on persons who have disabilities.” (USDHHS, 1993, p. 2) The chronicity and multiple complications of diabetes demand comprehensive long-term management by healthcare members who understand and provide quality diabetic care as outlined in the ADA standards.

There is some confusion in the literature regarding the use of the terms guidelines and standards with authors frequently using the two terms interchangeably. Eddy (1990) described guidelines as practice policies which apply to clinical interventions that have well-documented outcomes, but whose outcomes were not clearly desirable to all patients. Although they were the preferred clinical practices, these guidelines were flexible and could be tailored to the needs of individual patients. Standards, however, described practices with well-documented outcomes and virtual unanimity among patients about their desirability. A standard, being a relatively strict rule encompassing the best clinical decision, allowed for little deviation.

Based on the distinction between guidelines and standards, most of the literature available on diabetes mellitus provided guidelines for care of the diabetic patient. Fewer articles presented standards as criteria for diabetic management. Sources of national standards include health organizations such as the National Diabetes Advisory Board, the

American Association of Diabetes Educators, the Juvenile Diabetes Foundation, the American Dietetic Association, and the American Diabetes Association. A review of US literature revealed that articles may have addressed standards; however, there was a scarcity of articles dealing with the actual use of standards as a means of measurement for diabetes.

Deeb, Pettijohn, Shirah, and Freeman (1988) demonstrated the willingness of providers to change their practice habits to comply with recommended standards in a study by the Florida Diabetes Control Program (DCP). This study reviewed medical records from three intervention and three control primary-care centers over a two year period. Recommendations from The Prevention and Treatment of Five Complications of Diabetes: A Guide for Primary Care Practitioners (Guide) (1983) were used by Deeb et al. as standards with focus placed on visual impairment, lower extremity problems, renal problems, and blood pressure.

No hypothesis, conceptual framework, or literature review was provided. The authors presented a good background for the for the purpose of the study. However, they did not provide an in-depth description of the ADA's study which had stimulated their own research project.

The Florida DCP study sought to document the current level of care provided for complications of diabetes in the primary care setting, provide professional and patient education, and evaluate changes in the practice patterns. Only interventions which the Florida DCP felt it could afford to institute statewide were used. Professional education included a two-day seminar focusing on the diagnosis and treatment of the five preventable complications of diabetes as defined in the Guide. Other interventions included as-

signment of a nurse liaison/coordinator for the diabetic program at each intervention site, quarterly consultations with the Florida DCP, and education modules for patient education.

Six federally funded primary care centers in Florida were used; both control and intervention groups consisted of two rural centers serving migrant patients and an urban site. Intervention sites averaged 35,000 patient visits, had an average staff of eight physicians (three of which were National Health Service corps assignees), consisting of family physicians, internists, pediatricians, and obstetricians. Five of the physicians were internists or family physicians. The control sites averaged 25,000 visits and had an average of six physicians, with two assigned by the government. No other demographic information was available regarding the staff.

A procedure manual and a standardized data-collection instrument were developed and the nurse coordinators from the three intervention sites and the DCP professional staff were trained to perform the audits. No further information was available regarding this training or the tool used. To ensure audit standardization and data validity, auditors sampled each other's work utilizing a random sample of 25 records per site. The correlation rate was 98%.

All medical records at the intervention site with the diagnosis of diabetes were identified and were audited at the beginning of the program and after one year of project activity. Records at the control sites were only audited once during 1984 and 1985, the same period of time covered by the intervention sites, but data obtained from these years was collected as two separate data files. Records with at least one visit in each of two consecutive years were defined as eligible for review.

At the intervention sites, 648 records were reviewed the first year. Of the 600 records reviewed in the second year, 201 were new patients, 399 were reviewed both years, and 249 were inactive from the first year. At the control sites, 381 records were reviewed the first year and only 237 were reviewed the second year.

Statistical analysis was performed utilizing Statview, Brainpower, Calabasas, CA. Statistical significance was tested with unpaired t tests and χ^2 analysis at $P < .05$ level. Demographic information for the intervention sites was as follows: mean age 60.1 yr.; males 33%; Whites 32%, Blacks 45%, Hispanics 23%; duration of diabetes 10.4 yr.; insulin-treated 43%, oral agents 48%, diet 8%. Demographic data for the control sites was as follows: mean age 57 yr.; males 24%; Whites 29%, Blacks 53%, Hispanics 18%; duration of diabetes 8.4 yr.; insulin-treated 48%, oral agents 42%, diet alone 9%. The mean age, duration of diabetes and sex distribution were different at the .05 level.

The authors provided a detailed description of data results supported by a table devoted to each study group. Changes of statistical significance were summarized. At the intervention sites fundal exams (not specified as dilated) increased from 11 to 46%, retinopathy referrals increased from 9 to 43%, (however, 100% of patients were instructed to see an ophthalmologist); urinalysis increased from 69 to 94%; and history of foot problems increased from 45 to 73%, examinations of lower extremities increased from 66 to 94%. There were no changes of statistical significance in the control sites. A last blood pressure of ≥ 140 mmHg systolic or ≥ 90 mmHg diastolic was present in 64% of patients the first year, and 56% in the second year in the intervention group. There were no changes of statistical significance noted in the control group.

Following this study the Florida DCP implemented the Guide in state and federally funded primary-care centers based on the belief that examination for complications was the first step in reducing morbidity and mortality. The program also included a patient-education component.

In their discussion of the study, Deeb et al. (1988) stressed the importance of the documentation of care utilizing retinal exams, the least properly recorded of the required exams, as an example. Although nurses reported that 100% of the patients at the intervention sites were instructed to see an ophthalmologist, over half of the patients did not receive this service. The authors speculated that the reasons may have been financial cost to see a specialist or travel difficulty. The urban control site documented 5% lower extremity exams compared to approximately 50% documented lower extremity exams in the rural control sites. This difference persisted during the second year. Deeb et al. suggested further research was necessary to explain the persistent difference.

The authors made brief reference to a study by Adamson and Guillon (1986) which had obtained similar results however, in-depth description of the study was not presented. They also cited a study of family-practice residency teaching programs which had similar results regarding patients lost to tracking. Because demographic and diabetic information did not predict continued clinical follow-up, the authors felt that the patients were a transient population which made it difficult to perform long term follow-up without increasing costs and improving tracking abilities.

Deeb et al. summarized three benefits of their study stating it 1) confirmed the importance of working with primary-care physicians to improve the search for diabetic complications; 2) indicated the ability of the DCP to improve complications-related care

and document barriers; 3) provided the framework for intensive public health programs aimed at reducing complications of diabetes. The authors did not address limitations of their study.

Fain and Melkus (1994) conducted a descriptive study examining the practice patterns of six nurse practitioners. Background of the problem, though brief, included several citations; no in-depth description of the references was provided. The authors stated that standards of care were critical in measuring outcomes and were a means of monitoring care through early detection and prevention measures. The ADA had developed a position statement summarizing the minimum standards of care for diabetic patients. Fain & Melkus also noted a change in the role of the nurse practitioner and the value of the practitioner today referring to the Diabetes Control and Complications Trial which verified the importance of the nurse's role in managing patients with diabetes. Previous studies of primary care physicians reflected the need to more widely implement the ADA standards. The problem was the lack of documentation regarding the adherence of nurse practitioners to these standards. The objective of this study was to determine to what extent NP practice patterns of diabetes care were consistent with standards of care suggested by the American Diabetes Association.

The location of the study was an ambulatory primary-care center in conjunction with a 1,000 bed teaching hospital in an urban setting. More specifics on the location were not provided. More than 75% of the patients seen in the clinic had diabetes.

Although demographic information was collected regarding the NPs, it was not provided in this article. Description of the NPs and their practice was as follows. The six NPs were masters-prepared, certified, were autonomous in caring for their patients with

cross-collaboration with physicians upon request. Five of the six NPs had been in practice between five and ten years. None were certified diabetic educators. All reported becoming clinically competent to care for their diabetic patients on the job.

The criteria for selection in the study required that the patient must have been diagnosed with diabetes longer than two years and received care at the ambulatory primary-care clinic site within the last 14 months. The sample consisted of 23 men and 55 women with ages ranging from 28 to 82 and a mean age of 56 +/- 12.8 years. Sixty-eight percent had NIDDM and 32% had IDDM. Other demographic information was not provided.

Utilizing a Diabetes Quality Assurance Checklist developed by the Diabetes Research and Training Center at Albert Einstein College of Medicine, the authors audited a convenience sample of 78 charts with a proportionate number of charts from each practitioner. The checklist was meant to be used in an ambulatory setting for a 10 to 15 minute chart review of documented yearly medical care. A sample of the checklist was included in the article. Four major categories were studied: referrals, glucose evaluation, nutrition, and foot care. The chart reviewers indicated whether or not standards of care were carried out; interrater estimates with r values ranged from 0.73 to 0.94. No information was provided regarding the number, qualifications, or training of the reviewers.

Fain and Melkus stated each of the four ADA standards before presenting the resulting data which indicated a gap between the standards of care and the degree to which these minimum standards were being met. The study indicated that 50% of patients were not being properly referred for ophthalmic examinations and/or EKG. Ninety percent of patients received adequate glucose evaluation; but only 57.7% indicated annual HbA1c testing and 23.1% received no testing at all. Thirty-two percent of the charts indicated no

recommendation of home glucose monitoring. Only 43.6% of patients were referred to a registered dietitian; 73.1% had some form of diet intervention documented. Comprehensive foot exams were indicated in 23.1% with a 53.9% referral rate to podiatrists.

The authors stressed the benefits of ophthalmologic exams, EKGs, home blood glucose monitoring, glycosylated hemoglobin, good nutritional management, and proper foot care in patients with diabetes. Although they cited several references to substantiate their rationale, the only information provided regarding these sources was found in the reference list.

Fain and Melkus did not make any suggestions for further studies although they did identify the fact that this study was carried out in only one institution and involved six NPs as a limitation. They concluded the article stating that although NPs constituted a large group of health professionals providing care to people with diabetes, they had not been targeted for professional education in diabetes care and management. Primary-care practitioners needed to understand the importance of diabetes care and management to detect and reduce diabetes complications.

Utilizing survey data from a nationwide stratified probability sample of primary care physicians, Kenny, Smith, Goldschmid, Newman, and Herman (1993) provided a brief analysis of the physicians' adherence to clinical and laboratory recommendations for Type I (IDDM) and Type II (NIDDM) diabetes mellitus. The data was derived from the Survey of Physician Practice Behaviors Related to Diabetes Mellitus conducted by the National Institute of Diabetes and Digestive and Kidney Diseases between June and December 1989. Because of the vast amount of data accumulated from this study, the results were presented in more than one report.

Kenny et al. (1993) provided a very brief description of the problem addressed in this study noting that appropriate preventive services could decrease morbidity and cost of diabetes complications. Recommendations for these services were available from reputable literature sources such as the ADA position statement: Standards of medical care for patients with diabetes mellitus, ADA's Physician's Guide to Insulin-Dependent (Type I) Diabetes and Physician's Guide to Non-Insulin-Dependent (Type II) Diabetes and the CDCP's The prevention and treatment of complications of diabetes mellitus in A Guide for Primary Care Practitioners. However, despite the availability of these recommendations, little was known regarding actual physician knowledge and adherence to these recommendations. No hypothesis, conceptual framework, or literature review was provided. Kenny et al. briefly described the research design and methods citing an article by Siebert, Lipsett, Greenblatt and Silverman (1993) which addressed the design and methods in more detail. The following information was taken from Siebert's article.

A stratified probability sample of 3481 primary care physicians engaged in practice in the continental US was compiled using the files of the American Medical Association and American Osteopathic Association. A sample size of 400 was needed in each of the four specialty groups used (Family Physician, General Practitioner, Internist, and Pediatrician) to detect 5% differences between specialties at the 95% Confidence Interval (CI). Sample sizes were Internal Medicine (IM)=921, Pediatrics (PD)=835, General Practice (GP)=911, and Family Practice (FP)=814.

Two questionnaires were designed by experts in diabetes and questionnaire design: one for pediatricians containing 33 questions about IDDM and one for the other specialties containing 37 questions about both NIDDM and IDDM. The questionnaires

were pretested by 9 IM/FP/ PD physicians practicing in Maryland and revisions were made as indicated. The questionnaires were sent by mail along with a check for \$25 as incentive to participate. Non-responders were sent a second copy of the questionnaire. Non-responders to the second copy were contacted by phone.

A brief screening questionnaire determined eligibility. Ineligible physicians were those whose self-reported specialty was not GP, IM, PD, or FP; self identified as resident physicians; did not treat IDDM patients or < 10 NIDDM patients; spent < 50% of their time in direct patient care or consultation; or did not speak English. Eligibility rate derived from the responses to the screening questionnaire was 65.6%. After completing the mail survey phase, the eligibility rate among responders was 74.3%.

Siebert et al. (1993) utilized three tables to summarize the data. Table 1 summarized the final response status for the entire sample of 3481 physicians. The study had a response rate of 65.7% with a total eligibility rate of 43.2%. Pediatricians had the highest ineligible rate (39.2%) largely because they did not see IDDM patients; they also had the lowest non-response rate (19.5%). Approximately 15% of the general practitioners maintained less than full-time practices; GPs also had the highest refusal to participate rate (16.2%). No regional difference was noted in response status; physicians 46 years of age or older had a slightly higher response rate. Table 2 summarized the response status of all surveyed physicians. The response rate after the mail survey phase was 55.3% with an eligibility rate of 74.3%. Approximately half of the non-responders were contacted by telephone with a response rate of 46.9%. Eligibility rate among the telephone responders was 19.6%. Table 3 compared the specialty classification from the AMA/AOA file and

the physicians' self identification. A substantial number of the AMA/AOA-classified GPs called themselves FPs; a smaller number of FPs identified themselves as GPs.

Physicians were asked how frequently they performed seven clinical and laboratory procedures for both IDDM and NIDDM patients. Pediatricians were asked to respond only to treatment of IDDM patients. Providers were not questioned regarding their awareness or reviewal of published recommendations. Evidence of adherence was defined as the service performed at least as often as recommended.

Logistic regression was used to investigate the relationships between adherence and the physician specialty, age, and type of diabetes being treated. The authors reported "the presence of second and third order interactions were determined before model reduction and was found to be insignificant. Significance was assumed to be below the 0.05 nominal level unless otherwise indicated (Kenny et al., 1993, p. 1507).

Siebert et al. (1993) included an appendix which explained in detail estimation and analytic procedures (weighting procedures, base weight, non-response adjustments, final weights, and variance estimates).

A total of 1434 physicians completed responses for the clinical portion of the questionnaire; IMs tallying 29% of the total responses, FPs 31%, GPs 18%, and PDs 22%. The age distribution was similar within the specialties with the GPs older on the average.

Kenny et al. (1993) provided a general analysis of the data results, however, the two accompanying tables provided detailed figures for recommended treatments according to each specialty by age division (<39 yr., 40-54 yr., and >55 yr.). Recommended treatments included semiannual teeth/gum exam, annual fundoscopic exam, quarterly

B/P, annual circulatory exam, semiannual foot exam, annual urinary protein, annual BUN/creatinine, and annual fasting cholesterol/triglyceride. In all treatment recommendations, adherence for management of IDDM patients was higher than for NIDDM patients. In general, approximately 33% of IMs, FPs, and GPs reported semiannual teeth/gum exams, whereas PDs reported a significant higher adherence rate (64%). The following results dealt with NIDDM patients only. Adherence rates to fundoscopic exams declined significantly with age: IMs averaged 87%, FPs 87%, and GPs 77%. The majority of physicians measured blood pressures at least quarterly; GPs had the highest adherence rate (76%). Age was not a significant factor. Self-reported adherence to the recommended annual circulatory exams ranged from an average of 76% (GPs) to 89% (IMs). A significant difference was noted between specialties with age significance noted but varying with each specialty. The rate of semiannual foot exams was significantly related to physician age with IMs having the highest reported rate (an average of 57%). Adherence to the annual measurement of urinary protein was poor and significantly related to specialty with GPs rating the highest average (36%). Physicians reported high adherence to recommendations for annual BUN/creatinine blood tests with an average of 93% or more in all three specialties. Older physicians tended to adhere to recommendations less often. Adherence to annual fasting cholesterol/triglycerides levels was high ($\geq 92\%$) for all specialties and ages although a slight decline with age was noted in the GPs.

Kenny et al. reflected that a possible cause for some differences between specialties could have been medical training and experience (especially IMs and PDs). Results suggested that continuing medical education be targeted to the older physicians and certain specialty groups.

The authors concluded the differences between IDDM and NIDDM adherence to treatment recommendations may have reflected a perception that NIDDM was less serious and thus received less preventive services even though NIDDM constituted the most cases of diabetes and some complications were more common in NIDDM.

The authors listed three potential sources of bias in their analysis of the survey: a) adherence rates were self-reported and may have overestimated actual practices; b) responding physicians may have responded at different rates than non-responders with a likelihood that non-responders would adhere less to practice recommendations; c) physicians were not asked about their adherence based on the age and duration of the patient being treated.

Information of interest not found in the study included what guides or standards the physicians were familiar with or following in their practice.

Kenny et al. (1993) recommended adequate review and validation among physician peers and a more active patient role in their primary care as helpful solutions. Note, however, that increased patient participation, while a desirable goal, does not address provider adherence to available recommendations. The authors reported that patient load, time restraints, office-based systems, availability of service, and reimbursement policies affected the providers' behaviors and suggested that future interventions address these factors.

Payne et al. (1989) reviewed the charts of 544 patients to determine how frequently preventive care was provided to diabetic patients in the Denver Department of Health and Hospitals (DDHH) in 1984. (Preventive care included fundoscopic exams, ophthalmologic referrals, foot exams, and assessment of cardiovascular risk factors.) A

magnetic search of DDHH billing tapes for ICD 9 code for diabetes mellitus produced 1196 patient names from which 50% were randomly selected for the study. Of this sample 17 charts were not available and 41 patients did not have diabetes leaving a total enrollment of 544. Chart reviewers were trained and interrater reliability was >95% in all variables except family income. Description of the training process was not provided.

The study was published under Short Reports in Diabetes Care and did not include an hypothesis, theory, conceptual framework, literature review, or a description of the tool or its development. A brief reference was made to two other studies by Bailey et al. (1985) and Deeb et al. (1988) which had obtained similar results. A brief description of the sample included the following: mean age 55 years; females 64.5%; Hispanics 39.6%, Blacks 34.4%, whites 23.4%; median family income \$4685/ year (per chart); coverage by Medicaid 33%, Medicare 33%, and no insurance 38%; NIDDM (Type II) 78.1%, IDDM (Type I) 11.4%, Gestational Diabetes 0.2%, and no type recorded 10.3%; insulin-treated 53.7%, oral hypoglycemics 30.7%, both 2.4%, and diet alone 13.2%.

Although the authors did not directly address the issue of upholding standards for diabetic care, they concluded that “most patients did not receive recommended preventive care during the study year” (Payne et al., 1989, p. 745). They did not specify in the article who made these recommendations but the reference list included a journal article entitled Preventable complications of diabetes mellitus and a publication by the National Diabetes Advisory Board (Department of Health and Human Services) entitled The Prevention and Treatment of Five Complications of Diabetes: A Guide for Primary Care Practitioners.

Lack of preventive care was reflected in that fact that only 13.1% of the patients were referred to ophthalmology and only 34.1% had recorded fundoscopic exams. Forty eight percent had recorded foot exams; 45.2% of the charts contained an assessment of smoking status; 67.8% had serum cholesterol values. The mean \pm SE number of primary care visits was 5.7 (\pm 0.22) with a total of 6153 outpatient visits and 293 hospitalizations. Among patients seen greater than ten times in the primary care setting, preventive care was not provided to 30% of the patients.

Payne et al. did not address the limitations of their study nor make suggestions for future studies. They did suggest some possible causes for the low preventive care provided. Availability of timely ophthalmology referral services was a problem. Poor documentation was a possibility but more likely preventive care was overlooked. The authors felt cost was not a major problem because the patients, though poor, were seen frequently and preventive care could have been provided by primary care practitioners. The authors suggested an increase in practitioner awareness of appropriate preventive care, chart or computer-based reminders, and improved accessibility of referral care could help increase preventive care for the diabetic patients.

In her study Testing for blood glucose by office-based physicians in the US, Harris (1990a) stated the measurement of blood glucose was essential in the diagnosis and management of diabetes, assessing efficacy of treatment, and prevention of acute events. Recommendations stressed that glucose test be performed at each physician visit via fasting or random blood glucose or glycosylated hemoglobin although this depended upon the form of therapy. Harris cited ADA's The Physician's Guide to Type II Diabetes (NIDDM): Diagnosis and Treatment (1984) and Physician's Guide to Non-Insulin De-

pendent (Type II) Diabetes: Diagnosis and Treatment (1988). Description of the problem was followed by a clearly defined purpose: to investigate how frequently physicians in the US perform tests for blood glucose on their diabetic patients. Although Harris (1990a) cited references throughout her article, no in-depth review of literature was presented nor was there discussion of a hypothesis, theory, or conceptual framework. A summary of her research design and methods follows.

The National Ambulatory Medical Care Survey (NAMCS) was conducted from March 1985 to February 1986. The 2879 physicians were selected from the files maintained by the American Medical Association and included office-based physicians engaged in patient-care activities. The actual data was collected by the physicians and their office staff. During a randomly assigned seven-day period, a patient-record form was completed for a random sample of approximately 25 patients seen by each physician. No information was provided regarding the actual process of selection. To produce national estimates of physician visits for diabetes mellitus, data was weighted according to the probability of inclusions of the visit in the survey by physician specialty, geographic location, practice size, and sampling rate. "Standard errors of estimates were interpolated from tables of standard errors for NAMCS data published by the National Center for Health Statistics [1988]" (p. 420).

Harris (1990a) utilized five tables to display her data. Table one showed distribution of diabetes-related visits in the NAMCS sample and this data extrapolated to all US office-based physicians. According to Table 2 (Age-specific distribution of visits) data estimated that a total of 21.3 million visits involving diabetes were made to office-based

physicians in 1985 representing 3.3% of all visits made during that year. The proportion increased with age resulting in 7-8% for patients aged 55-84.

Table 3 reported distribution of visits for diabetes. Primary-care specialties obtained >78% of the visits. This was subdivided into Internal Medicine 33%, General Practice 21.7%, Family Practice 20.6%, and Diabetology/endocrinology 2.5%. Clearly, general management of diabetes was being done by providers who did not specialize in diabetes.

Table 4 reported frequency of blood and urine glucose testing. Forty-eight percent of primary care specialists ordered blood glucose tests alone, 20.9% ordered blood and urine tests, 5.9% ordered urine glucose tests alone, and 24.9% ordered none.

Table 5 (Frequency of blood glucose in visits to primary-care physicians) showed characteristics of diabetes visits to rate of testing for blood glucose. The major factor influencing rate of testing was whether diabetes was considered to be the primary diagnosis during the visit (78.9%) or recorded as second (56.9%) or third (42.7%). There was a lower testing rate with decreasing number of physicians in the practice: group practice 77.4%, solo practice 64.2%. Differences in testing rates were also found to be higher for health maintenance organizations (83.6%) and other pre-paid plans while Blue Cross/Blue Shield (63.7%) had nearly the lowest rate of tests for blood sugar. Harris (1990a) attempted to explain why absence of tests for blood glucose was 31.2% listing failure to record an ordered test and failure to report glycosylated hemoglobin results as blood glucose tests collected.

In her discussion of data results, Harris (1990a) cited several ADA recommendations. NAMC estimated 16.75 million visits to primary care physicians during 1985,

yielding an average of 2.7 visits/diabetic patient per year compared to the ADA standards of at least quarterly visits for insulin-treated patients and at least semi-annual visits for non-insulin treated patients.

ADA recommended that glycosylated hemoglobin be determined at least semi-annually in all patients (preferably quarterly in insulin-treated patients and non-insulin patients with poor control). The ADA suggested that fasting glucose levels could be useful to judge glycemic control in non-insulin dependent diabetics. A random glucose level could be compared to the values obtained in home monitoring, but ADA cautioned providers that interpretation of these results must be made with care. NAMCS reported 69% of visits involving blood glucose levels, an average of 1.9 times per patient. However, the type of glucose test was not recorded, information which Harris felt would be important to develop in a future study. Although not clearly stated as a limitation, Harris reported that because NAMCS was a visit-based survey, it was weighted toward diabetic patients who saw physicians more frequently.

The objective of the study by Mayfield et al. (1994) was to evaluate the adherence to minimum standards for diabetes care in multiple primary care facilities of the Indian Health Services (IHS). During the fiscal year 1992 (1 Oct. 1991 to 30 Sep. 1992) the IHS performed medical record reviews on 6959 randomly selected charts from the diabetes registry of 138 participating facilities. The sample represented 79% of the diabetics served by IHS. The sample size from each facility was sufficient to provide estimates plus or minus 10% of the true adherence to that facility with a confidence greater than or equal to 90%.

The IHS Minimum Standards of Care differed from ADA recommendations by suggesting a blood glucose level at every visit, health maintenance procedures that included immunizations and CA screening, and annual urinary dipstick assessment for protein.

The authors cited various sources throughout the article; however, no description of the references was provided nor did the authors present a hypothesis, theory, or conceptual framework. The medical record review which included the definitions of active patients and preventive care was developed concurrently with the standards. An active patient was a diabetic patient who lived in the geographic area, was enrolled at the clinic, and was seen on a regular or infrequent basis for care. A complete foot exam included examination of the skin, bony deformities, and the neurological and vascular status of the lower limb. An eye exam was a dilated fundoscopic exam by an eye specialist or trained primary-care provider, or a fundal photograph. The medical record review and the standards were periodically reassessed by diabetes control officers who also developed a medical record review manual. This manual included instructions for chart selection, uniform definitions, and a sample chart abstraction form. IHS providers were given copies of the IHS standards and summaries of the medical record review. A detailed description of the tool was not included in this article.

The diabetes control officers, 12 health professionals who facilitated diabetes-related activities in the 12 IHS administrative regions, trained other Diabetes Program staff and professional staff assisting with the medical record review. No details regarding this training were provided.

Following are characteristics of the IHS diabetic population: 61% were females; 52% of the patients were between 45 to 64 years of age; 25% were over 65 years of age; one-third of the patients had diabetes a minimum of 10 years; 52% were overweight; 30% were obese; half of the patients were treated solely with oral hypoglycemics, 19% with diet alone, and almost one-third were treated with insulin.

Data was entered into a computer using an Epi-Info Software Program distributed by the Diabetes Program. Each facility received a report of the percentage of adherence to various care items for their immediate use. Summary rates for each care item and corresponding confidence intervals were constructed by multiplying each facility's percentage of adherence by a weighting factor proportional to the number of diabetic patients in the facility's diabetes registry. This data was presented in a graph as well as summarized in the body of the article.

Mayfield et al. included a table entitled "Benchmarks for comparison of diabetes care" comparing their results to those from ten other studies on such topic areas as fundoscopic exams, foot exams, dental exams, blood pressure, blood glucose, and urinalysis. However, the absence of a legend made it difficult to interpret all the information provided. The studies used four different methods of data gathering: provider self-report, patient survey, medical record review/chart audit, and computerized billing records or utilization data. Mayfield et al. briefly described the major weakness of each data collection method used in these studies, however, an in-depth evaluation was not included. The provider self-report, used for the largest and most comprehensive studies, exceeded actual performance and was prone to respondent bias. Patient surveys had similar limitations. The medical record review, the most frequently used method, was generally used to

evaluate an intervention rather than routine care, sampled only a few clinics, and covered a limited number of items. Analysis of administrative data was less expensive than chart review but was limited by provider underreporting, misclassification, and the lack of specific codes for procedures. The rates from the IHS medical record review were comparable to record reviews of routine care and administrative data, but lower than audits after intensive intervention programs and self-report surveys of patients or providers. Studies in this table were included in the reference list.

Weight, B/P, creatinine, and EKGs obtained the highest rates of adherence with scores of 87%, 87%, 81% and 80% respectively. These were followed by urinalysis, blood sugar, cholesterol, and pneumovax with scores of 78%, 75%, 74%, and 70%. Adherence to triglycerides rated 67%; diet instruction rated 57%; and adherence to foot and fundoscopic exams rated 53% each. Exercise was addressed in 42% of the records, tobacco use was recorded in only 32% of the records. Dental exams received the lowest compliance rating with a score of 25%.

The authors listed five possible reasons for the differences between IHS standards and the observed care: a) definitions which were too broad (i.e. active patient included many patients who attended the clinic infrequently); b) physician lack of awareness of or disagreement with the standards; c) resource and personnel constraints; d) patient-specific issues that may have altered patient's willingness to be seen for diabetic preventive care; e) the influence of mechanisms of health-care delivery on adherence to standards. Non-provider procedures such as B/P or those done under protocol were performed more often than physician activities such as foot exams.

Some obvious weaknesses in this rational were apparent. One must remember that the purpose of the review was to see if the providers, not the patients, were adhering to the standards. Also, note that all providers were given a copy of the standard along with a summary of the medical record review. It is also puzzling that the IHS would require standards knowing their facilities lacked the resources or personnel needed to conform to them.

The authors named four potential limitations of their data and the “generalizability” of their findings to other primary-care settings: a) IHS providers tended to be younger than the general population of primary-care providers; younger age was associated with higher rates of compliance (the authors cited Kenny et al., 1993); b) IHS experienced a 25% annual turnover of physicians which may have resulted in disorganization and discontinuity in follow up; c) the patient population was younger, poorer, more rural than the general US population and possessed many language and cultural differences; d) the high prevalence of diabetes in this population had resulted in increased family and community awareness of diabetes. No data was available regarding impact of demographic and social factors on the adherence to standards for diabetes care.

Mayfield et al. (1994) listed advantages and disadvantages of the assessment system developed by IHS: the use of uniform definitions and methods for data collection and comparison, inexpensive software and portable personal computers, and available facility report for immediate use versus difficulty developing consensus on definitions, expense of medical record reviews (\$25-100 per chart), and untimeliness of retrospective reviews. The IHS has since begun to integrate diabetes care assessment and registry into their computer-based patient record system to eliminate duplication of data entry and provide

physicians with reminders of care needs with each patient visit. No suggestions were included for future research.

The objective of the study by Brechner et al. (1993) was to assess whether adults with diagnosed diabetes in the US were receiving recommended eye exams for detection of diabetic retinopathy and what factors were associated with receiving them. The authors began the article with a precise and building description of the problem and its importance. Diabetes was the leading cause of new blindness in ages 20-74 in the US. The prevalence of retinopathy 15 years after diagnosis of insulin-dependent diabetes was 100%; twenty-one percent of non-insulin-dependent diabetics had retinopathy at the time of diagnosis. By 20 years after diagnosis, 60% of NIDDM had some degree of retinopathy. Laser therapy applied early in the course of the disease could reduce the risk of visual impairment. Significant retinopathy could exist without visual symptoms until the disease was advanced and less amenable to treatment. Therefore, the recommendation for patients with IDDM was to have annual dilated eye exams after five years of diabetes and NIDDM have a dilated eye exam at the time of diagnosis and annually thereafter. The authors cited the American Diabetes Association, Center for Disease Control and Prevention, American College of Ophthalmology, and American College of Physicians as sources for these recommendations.

A review of literature was not provided, although sources were cited throughout the article and mention was made of two other studies which had obtained similar results (Sprafka, 1990 and Witkin and Klein, 1984.)

The authors analyzed data from the 1989 National Health Interview Survey. This included a basic questionnaire utilized by trained interviewers from the U. S. Bureau of

the Census conducting personal household interviews, making repeated visits to the home when respondents were not immediately available. Response rate had been 95-98% over the years. Accuracy of coding of the data was maintained through validation checks. Validation procedures were not described.

The 1989 sample, aged 18 years and older, totaled 84,572. A special questionnaire on diabetes was included. A screening question identified 2829 persons reported to have diabetes. Non-response to a detailed questions on diabetes was 4.5%. The final sample size of enrolled subjects with diabetes diagnosed by a physician was 2405 (IDDM=124, NIDDM =2268 of which 922 were treated with insulin, and type unknown= 13). Table 1 listed the nine questions related to ophthalmologic care in diabetes.

Univariate analysis and multivariate regression analyses were performed using SAS with appropriate sampling weights to provide estimates that were representative of the US population.... Standard errors of means and proportions were estimated using the Taylor Series linearization method and were calculated by the SEDUDAAN computer program.... Two-tailed large sample z tests were used to test for significant differences in means and proportions. Logistic regression using the RTILOGIT program was used to estimate the effects of variables on whether NIDDM subjects had had a dilated eye exam the past year (Brechtner et al., 1993, p.1715).

The authors utilized graphs and tables to present data on demographic and medical information and to clarify the discussion. Reported characteristics of US subjects, 18 years or older with diabetes, included age, sex, race, income, education mean, age at diagnosis, duration of diabetes, parental history of diabetes, regular physician for diabetes, diabetes education class, and health insurance according to type of diabetes (IDDM,

NIDDM with insulin, NIDDM without insulin). Substantial differences were found between IDDM and NIDDM patients. Fewer differences were found between NIDDM patients receiving insulin and those not receiving insulin. NIDDM patients receiving insulin were more likely to be Black and less likely to be White, were younger at the time of diagnosis, had a longer duration of diabetes, and were more likely to attend diabetes education classes.

Forty-nine percent of all diabetic persons 18 years or older in the US had an annual dilated eye exam. This statistic included 57% of IDDM patients, 55% NIDDM patients treated with insulin, and 44% NIDDM patients not treated with insulin. Only 38% of NIDDM patients with a diagnosis of one year or less had a dilated eye exam in the past year despite the recommendation that all NIDDM patients have a dilated eye exam at the time of diagnosis. Fifty-nine percent of IDDM patients with a diagnosis of 5 years or more had a dilated eye exam in the past year despite recommendations for annual exams. Thirty-three to forty-seven percent of patients with a history of retinopathy had not had a dilated exam in the past year nor had 39 - 49% of patients with a 15 year or more history of diabetes. NIDDM patients without insulin had lower percentages for all aspects of eye care.

In general the proportion of diabetic patients receiving yearly dilated eye exams increased with older age, higher income, higher education, and attendance in diabetic education classes. The probability of an annual dilated eye exam was not independently related to race, duration of diabetes, frequency of visits for diabetes, or health insurance.

Brechner et al. pointed out two potential limitations in their study. First, because the diabetes was self-reported, the study did not identify individuals who would not admit or did not know they were diabetic. However, the authors went on to say that validity studies had found more than 95% concordance for diabetes between self-report and the medical record. Of greater concern was the potential number of individuals who do not know they have diabetes. Approximately 50% of people in the US who meet National Diabetes Data Group criteria for diabetes are undiagnosed (Harris, 1990b).

The second potential limitation was the reliability and accuracy of the question “when was the last time you had an eye exam in which the pupils were dilated? This would make you temporarily sensitive to bright light.” (p. 1715) The authors reported a study by the Centers for Disease Control and Prevention (unpublished data, 1993) in which 99 (93%) of the 106 persons with medical documentation of a dilated eye exam in the past year reported having one. Of 144 persons reported having a dilated eye exam in the past year, only 99 (69%) had documentation of the exam in the medical record.

Brechner et al.(1993) concluded that a large segment of the diabetic population in the US was not receiving eye care to detect diabetic retinopathy and prevent visual impairment and blindness despite recommendations. The authors suggested either a lack of knowledge about conducting the exams or about the need for referring patients to eye care professionals called for training the primary-care providers. The authors did not make suggestions for future research studies or solutions to the problem.

In their evaluation of the Diabetes Control and Complications Trial and its effects on medical care for the diabetic, Harris, Eastman, & Siebert (1994) felt the medical care for diabetics in the US did not meet the ADA standards and listed several reasons. Barri-

ers included financial reimbursement for care by personnel who provided intensive management (e.g. dietitians and diabetic educators) and self-care techniques such as blood glucose monitoring; access by physicians to allied health-care professionals and specialists in diabetes complications; and problems with knowledge about treatment of diabetes and its complications among the non-specialist-primary care providers who manage the majority of diabetic patients in the US.

In his evaluation of the ADA standards, Kerr (1995) stated there had been little physician awareness of these standards and no published evidence of any impact of these standards on physician practice or diabetes mortality. Kerr felt that the biggest obstacles were the number of standards which made their use impractical in the busy office setting and the lack of a convenient instrument for tracking them. He divided the recommended medical interventions into two sections, those worth doing and those not worth doing, and categorized each intervention using one to four stars. Kerr's goal was to present an evidence-based approach to care of the Type II patient that is practical, strategically focused, and consistent with the family practice philosophy. Four stars meant the intervention was well supported by existing literature and these interventions were not discussed in detail. Three stars recommendations were derived from small clinical trials, case-control studies, or larger retrospective studies. Two stars were based on expert consensus (ADA standards); evidence-based recommendations for the general medical population reasonably extrapolated to diabetic patients; or evidence from a well-conducted experimental or physiological study that implied benefits from an intervention not yet proven. One star referred to policies or procedures which the author judged to be useful and in

keeping with the family practice approach. Kerr included a Diabetes Office Flow Sheet based on his approach.

CHAPTER THREE

The following chapter describes measures taken to protect the human rights of the patients whose medical records were reviewed and providers of these patients. It describes the development of the Diabetes Quality Assurance (DQA) Checklist to include the assessments for its reliability and validity. Included is a description of the pilot study of this research project and concerns that were addressed as a result. The design section includes details of the demographic information to be collected and a physical description of the DQA Checklist.

Human Rights

Verbal permission for this study was first obtained from the Directors of the Outpatient Clinics and the Medical Clinic at the proposed study site. A copy of the proposal was submitted to and written approval was then obtained from the Institutional Review Board, Research Administration at Uniformed Services University of Health Sciences and the Internal Review Board, Medical Education and Training at the Medical Center. A copy of the IRB approval was provided to the Outpatient Department at the Medical Center.

Steps were taken to protect the rights of the patients whose medical records were reviewed and the providers of these patients. Access to the master list containing names, social security numbers, and randomly assigned numbers was limited to the sole researcher. Medical records were obtained directly from Outpatient Records and were promptly returned following the chart review. Charts were not removed from the hospital setting by the researcher. Information from the medical records was kept confidential.

Data from the chart reviews was compiled together as a whole; no attempt was made to associate results with individual providers.

Instrumentation

This study utilized the Diabetes Quality Assurance (DQA) Checklist developed by Wylie-Rosett et al. (1992) to measure adherence to the ADA medical standards in a military medical health care setting. The DQA Checklist originally consisted of two sections: a Basic Assessment and a High-Risk Assessment and Intervention. Due to the added complexity and time requirements of High Risk Assessment and Intervention, only the Basic Assessment section was utilized in this study.

Wylie-Rosett et al. established the face validity of the instrument using a panel of seven diabetes experts who reviewed the items on the checklist, the scores assigned to each item, and the chart review protocol. The value of points assigned to each element was determined by clinical judgment and the consensus of the panel.

The reliability of the DQA Checklist was established using sample charts selected from two locations, a primary care clinic and a Diabetes Research and Training Center located in New York City, NY. The chart reviews were conducted by health psychology graduate students who had no previous training or clinical experience related to diabetes. The reviewers used a specific protocol that was developed to standardize chart-review procedures and to score the Basic Assessment and High-Risk Intervention and Assessment. The protocol defined the elements of care for each item on the DQA Checklist.

Both inter-rater and intra-rater reliability were assessed for the Basic Assessment and High-Risk Intervention and Assessment. Since only the Basic Assessment was used in the study the following data on reliability refers only to that section. The inter-rater

reliability compared the DQA Checklist scores obtained by two reviewers at the same point in time. The intra-rater reliability compared the scoring of the same charts by the same reviewer at two different times with the chart review encompassing a specified year of care.

In the original study, the two raters simultaneously scored a convenience sample of 23 charts (respectively, 11 and 12 charts from each site) that were scored again by both reviewers between five and seven weeks later. Pearson correlation coefficients and analysis of variance were used to assess consistency in mean scores between raters and stability over time. Kappa reliability was calculated for the dichotomous responses of the two reviewers for the Basic Assessment (p. 413).

The inter-rater reliability estimates indicated a high degree of agreement between the reviewers, with κ values of 0.91 and 0.94. The intra-rater reliability estimates indicated consistency over time with κ values of 0.75 and 0.84. The inter-rater kappa estimates were quite high in Time 1 and Time 2, with values ranging from 0.59 to 1.00. The intra-rater estimates were somewhat lower, with calculated kappa values ranging from 0.28 to 0.73 (p. 413-14). Wylie-Rosett et al. felt the lower estimates for intra-rater reliability were related to differences between Time 1 and Time 2 with respect to the time window included in the chart review. The original checklist was then modified to record inclusive dates to indicate the beginning and end of the time period included in the chart review.

Pilot Study

Validity and reliability of the DQA Checklist as described above, however, were established in a study utilizing a civilian population. Would this validity and reliability be relevant in a study that reviewed diabetic healthcare provided in a military outpatient clinic by military providers for former military members and their dependents? A pilot study, utilizing a military population, was performed to further assure the validity and reliability of the DQA Checklist and pinpoint any problems in the investigative process. The Checklist was compared to the 1994 Standards to determine the need for updates; none were found.

Prior to the pilot study, two diabetes experts, a university Associate Professor in the Department of Physiology and a Masters-prepared, military Nurse Practitioner, reviewed items from the Basic Assessment to further validate the Checklist. Each expert received an instruction sheet, a copy of the 1994 ADA Standards of Medical Care for Patients With Diabetes Mellitus, two evaluation sheets for the relevance of each element and the relevance of the numerical value assigned to each individual element, and a total grading scale. (See Appendices A, D, E, F, G.)

Utilizing the evaluation sheet marked relevance of element, the experts evaluated the relevance of each element using the scale of 4 to 1 provided. The number four represented an element which was very relevant; number three represented an element which was relevant; number two represented an element which was somewhat relevant; number one represented an element which was not relevant. Each evaluator circled the number representing his or her choice. (See Appendix H.) Elements rated two or less by both evaluators or elements whose scores varied by two or more points were examined further

to determine if changes were necessary. No elements received ratings of two or less by both experts. Only three elements (12%) received ratings with a two-point difference. Rater one felt home urine monitoring was very relevant; rater two felt it was somewhat relevant. The 1994 ADA standard stated that urine glucose testing was an alternative for those patients unable or unwilling to perform blood glucose testing or if the only goal was avoidance of symptomatic high glucose. Because urine glucose testing is essential when illness is present, this element was retained on the checklist. Rater one felt that tracking the number of footcare exams was very relevant. Rater two felt tracking footcare done once a year was somewhat relevant, whereas, tracking footcare exams done twice or more each year was relevant. The 1994 ADA standard recommended that the feet be examined every regular visit (quarterly or semiannually depending upon the treatment goal) and that podiatry referrals be made when appropriate. The footcare element was retained to help track the number of foot exams performed during the year. Rater one felt height measurement was very relevant, whereas rater two felt that this was somewhat relevant. The 1994 ADA standard recommended height measurement be performed at every regular visit until maturity. However, most diabetes is either made manifest by obesity in genetically predisposed persons or is acutely caused by obesity (Gregerman, 1995, p. 985). Fain (1993) reported that approximately 60 to 75% of patients are obese when diabetes is diagnosed clearly indicating the need to monitor obesity through the height/weight parameters. Therefore, the element remained on the DQA Checklist.

The evaluation sheet marked relevance of assigned numerical value was used to evaluate the numerical value assigned to each element based on the same rating scale of 4 to 1 as previously described. Evaluators circled the number representing their choice.

Again elements whose scores differed by two or more points were closely scrutinized as were any elements which were marked two or less by both raters. (See Appendix H.) Five elements differed notably in their scores. Rater one felt the designated points for blood glucose monitoring 1 - 3 times per year, glycohemoglobin measuring 1 time per year, home urine monitoring, and BP measurement were very relevant; rater two felt the point value was somewhat relevant for these elements. Rater one felt five points for one foot exam/year was somewhat relevant; rater two felt the point value was very relevant. Both raters felt that two points each for height and weight was somewhat relevant. Seventy-three percent of the elements received a score of three or four by at least one evaluator with less than a two-point difference.

Finally, utilizing the form titled total grading scale, the evaluators devised a total grading scale for the one hundred ten points possible to denote excellent, good, average, poor, and very poor physician compliance with the elements in the checklist. Space was provided for additional comments and suggestions. Scores that differed for each designation were totaled and halved with the following results: excellent - 86%, good - 80%, average - 75%, poor - 67%, and very poor - 57%. (See Appendix I.)

A Certified Adult Nurse Practitioner, fulfilling the role of Coordinator of Diabetic Education in a military Endocrinology Clinic, was also consulted and changes made based upon her input included adding LDL to the yearly laboratory values, changing urine protein to urine analysis, and specifying lab tests as yearly lab tests.

Revisions were made to the DQA Checklist. A pilot study was then conducted utilizing the methodology designed for the main study. Ten charts of Type II diabetics

seen in an Air Force medical clinic were randomly selected and reviewed utilizing the revised DQA Checklist and a Demographic sheet. (See Appendix B and C.)

Since Air Force outpatient clinics were not required to maintain statistics regarding patients with diabetes mellitus, no official roster of diabetics being seen in the medical clinic was available. Patient medical records were not maintained in the medical clinic itself; charts were located in Outpatient Records, in various clinics throughout the medical center, or at other medical facilities. Some medical records were handcarried by the patients. A master list of 529 patient names was compiled using names enrolled in the Diabetes Education classes sponsored by the medical clinic from 1 May 1994 to 30 April 1995. Each name was assigned a number from 1 to 529. Potential enrollees were then randomly selected using a Table of Random Digits. Requests for selected records were submitted to Outpatient Records via the Air Force form 250. A record temporarily checked out from Outpatient Records remained on the master list. A record maintained at a site other than Outpatient Records, handcarried, or whose location could not be determined was removed from the master list. Another randomized name was then selected as a replacement.

Medical records physically present were screened for eligibility. Eligibility was restricted to men and women age 55 years or older, diagnosed with Type II diabetes mellitus, who had received care at the medical clinic for longer than 12 months. Ineligible records were removed from the master list and returned to Outpatient Records. The first ten eligible records were enrolled in the pilot study. They were reviewed utilizing the revised DQA Checklist and a Demographic Information Sheet.

A second review process approximately three weeks later followed the same format. Nine of the original charts were obtained from Outpatient Records. The tenth chart was not available for review. Data was then entered into a computer and analyzed via the Statistical Package for the Social Sciences (SPSS) Software Program. Results from the pilot study were not incorporated into the main study.

Several areas of concern regarding the tool and the investigative process were addressed as a result of the pilot study. Points of clarification were as follows:

1. A provider would receive credit for “laboratory tests” if the order was clearly written in the chart; the lab results themselves need not be present in the chart. Providers were not given credit if it was unclear whether they were just planning to look at past lab results or actually order new labs (i.e. “check labs”).
2. Blood glucose levels done in the Diabetes Education class were not included in the total number of blood glucose levels drawn.
3. Dates and levels of each blood glucose and glycosylated hemoglobin were recorded on the checklist to assure reviewal accuracy.
4. “Ophthalmology referrals” included referrals to Optometry.
5. Credit was given for any “EKG” found in the chart performed during the study year; the rationale being that the IM provider may have seen that an EKG had been done by another department and may have chosen not to repeat the EKG unnecessarily.
6. Referrals to vascular specialists were accepted under “Podiatry referral” if the assessment involved the feet.
7. A list of acceptable parameters for vascular, neurological, and dermatological assessments of the foot was devised to assure consistency in the chart reviews. The “foot exam”

must include assessment of at least two of the following: vascular - pulses, capillary re-fill, skin temperature, femoral bruits; neurological - pain/ vibration/ touch, deep tendon reflexes; dermatological-signs of infection, presence of ulcers or lesions, dryness, color changes, nail conditions, hair presence/absence.

8. Credit was given to “Diet intervention specified” if diet was addressed by any health-care member as long as the specific diet was recorded.

9. “Nutrition noted” was restricted to the provider only; any reference made by the provider to diet or weight loss was accepted.

10. “Exercise” need only be addressed not prescribed. Exercise addressed by healthcare members other than the physician was also accepted.

11. “Smoking assessment” received credit if the patient was documented as a non-smoker on the problem list; a current history of smoking must be addressed specifically by the provider to receive credit.

12. Ancillary clinic visits such as Physical Therapy and Wound Clinic were recorded on the demographic sheet but not counted in the “total number of clinic visits” or “total number of providers seen”.

13. “Specified diet intervention” received credit if a discharge summary from a hospitalization mentioned a specific ADA diet.

Design

Following the pilot study, a main descriptive quantitative study involving chart reviews of documented medical care of thirty outpatient medical records was initiated. The same procedure, as outlined earlier, was used for random selection of charts and for data collection by the researcher.

Demographic information recorded included the patient's initials, chart identification number, age, sex, race, year of diagnosis, and total years as a Type II diabetic. Other information recorded on the demographic information sheet included total number of providers seen by the patient during the study year, total number of visits to the medical clinic, and total visits to other clinics and to the emergency room both at the medical center and other facilities. The last glucose and glycosylated hemoglobin were also recorded. (See Appendix C.)

The Basic Assessment portion of the DQA Checklist, with a 110-point maximum score, was based on the following point designations, by category:

- | | |
|--|-----------|
| 1. Referrals to specialists - | 18 points |
| 2. Monitoring of diabetes control - | 36 points |
| 3. General health care - | 20 points |
| 4. Foot care - | 15 points |
| 5. Cardiovascular assessment - | 9 points |
| 6. Laboratory tests related to complications - | 12 points |

The points assigned to the elements of care within each category were noted in parenthesis next to the corresponding item on the DQA checklist. Each element on the checklist was marked "yes" or "no" with points assigned for each yes answer circled. (See Appendix B.)

Demographic information and each yes or no answer were coded and entered into the computer. Scores for each element, section, and total point value were analyzed and the data calculated for percentage and frequency using the SPSS Software Program.

In accordance with the study proposal submitted to the University and Medical Center, attempts were made to protect the rights of the patients and providers throughout

the study. Validity and reliability of the DQA Checklist were assessed both in the original study and the pilot study for this research project and changes were made accordingly.

Data collection involved chart review of 30 randomly selected medical records utilizing the Basic Assessment section of the DQA Checklist with points assigned for each yes answer. Results were entered into a computer and percentages and frequencies were analyzed per the SPSS Software Program.

CHAPTER FOUR

This chapter presents a demographic description of thirty patients whose medical records were reviewed in this study. It addresses the number of patient visits to all clinics and the emergency departments as documented in the patient's record. It also assesses the frequency of referrals for eye, dental, and foot exams, exams for foot care and general care, assessments of cardiovascular risk factors and glucose monitoring, and yearly laboratory tests. Adherence to ten standards specifically addressed by the ADA Standards of Care and to overall elements of diabetic care found on the Diabetes Quality Assurance Checklist were also evaluated.

Sample description

A sample of 30 medical records of patients with diabetes mellitus Type II treated in a military medical clinic were randomly selected for manual review. The age range of the patients was 55 to 75 with a mean of 64 years ($SD=5.078$). Of the 13 men (all former active duty) and 17 women (all dependents of former active duty), 40% were White, 53.3% were Black, and 6.7% were Asian. The number of years that the patients had been diagnosed with diabetes ranged from 2 to 34 years with a mean of 9.9 years and a standard deviation of 7.7 years. Forty percent had been diagnosed 1 to 5 years, twenty percent 6 to 10 years, thirty percent 11 to 20 years, and ten percent 21 to 35 years.

Number of visits and providers

Diabetes mellitus is a complex disease with multiple potential complications. The participants in this study ranged from 55 to 75 years of age and had been diagnosed with diabetes mellitus Type II from 2 to 34 years. Elderly patients with diabetes mellitus deal

with not only the normal problems of aging but also the complications of diabetes mellitus. One could assume that multiple health problems encountered by the older Type II diabetic could result in more frequent visits to their primary health care provider or to ERs or various specialty clinics. The total number of visits to the medical center's outpatient clinics or its Emergency Department from 1 May 1994 to 30 April 1995 by patients with diabetes mellitus Type II ranged from 2 to 28 visits with a mean of 10.7 (SD=6) visits. The majority of patients (60%) visited the medical center 5 to 12 times during the year. Review of the medical records determined that specialty clinics concentrated their efforts on their specialty areas leaving the diabetic care per se to the medical clinic providers, although some studies and procedures overlapped on occasion (i.e. EKGs, foot exams, and laboratory studies).

The ADA Standards of Medical Care recommended that patients requiring insulin be seen at least quarterly and other patients be seen at least quarterly or semiannually. The frequency of visits depended on the type of diabetes, the blood glucose levels, complications, treatment goals and the presence of other medical conditions. Since the number of required visits for a diabetic depended on many varying factors, this study chose the minimum number of two visits as the comparative standard realizing this number would be higher for some patients. Table 1 shows the total number of visits to the medical clinic by patients with diabetes mellitus Type II from 1 May 1994 to 30 April 1995. The number of visits to the clinic ranged from 2 to 11 with a mean of 4.3 visits (SD = 1.9). All of the patients visited the medical clinic at least twice during the year, while approximately 63% visited the medical clinic at least 4 times during the year.

Table 1.

Total Number of Patient Visits to the Medical Clinic from 1/5/94 to 4/30/95.

Number of visits	Number of patients (=30)	Percent of sample
2	4	13.3
3	7	23.3
4	8	26.7
5	6	20.0
7	3	10.0
8	1	3.3
11	1	3.3

Twenty-five patients (83.3%) had visited other clinics in addition to the medical clinic. The number of visits ranged from 1 to 22 with a mean of 5.5 visits per year (SD=5.097). Nineteen patients (63%) visited these clinics 1 to 7 times during the year. The primary care clinic was frequented by 40% of the patients; ophthalmology and optometry saw 40% of the patients. Table 2 summarizes the number of patients who visited these clinics and the Emergency Department.

Fourteen patients (46.7%) had visited the emergency room at the medical center at least once during the year. The maximum number of visits per patient was three. There were no recorded visits to emergency departments or healthcare clinics outside of military medical facilities.

Table 2.

Number of Outpatient Clinic and Emergency Department Visits from 1/5/94 to 4/30/95.

Visiting sites	No. of pts.	Percent (n=30)
Emergency Department	14	46.7
Total Nonmedical Clinics	25	83.3
Primary Care	12	40.0
OB/GYN ^a	7	41.1
Ophthalmology ^b	12	40.0
Podiatry	9	20.0
Neuro/vascular	5	16.7
Orthopedics	4	13.0
Cardiology	2	6.7
Endocrinology	1	3.0
Family Practice	1	3.0
other specialty clinics ^c	12	40.0

^a Figures for the OB/GYN clinic relate only to the seventeen female patients.

^b Figures for Ophthalmology include Optometry visits.

^c Specialty clinics include Nephrology, Audiology, Hematology/Oncology, Dermatology, Urology and Arthritis and Connective Tissue Service.

Nine patients were hospitalized from 1 to 15 days during the study year for cataracts, cancer, total hip replacement, thyroidectomy, empyema, asystole and femoral bypass. Two patients were hospitalized twice.

Ninety-three percent (28) of the patients had their diabetes mellitus managed by one medical clinic provider from 1 May 1994 to 30 April 1995. Seven point four percent of these patients had a good A1C level (6 - 7), 22.2% had a fair A1C level (7 - 8), and 70.4% had a poor A1C level (>8). The remaining 7% (2) of patients managed by two

providers from the medical clinic, had a glucose level over 200 mg/dl and/ or a hemoglobin A1C >8.

The total number of outpatient providers seen by each patient ranged from 1 to 16 providers with a mean of 5.4 providers (SD=1.878) seen from 1 May 1994 to 30 April 1995.

Referrals

According to the ADA Standards of Medical Care continuing care for the diabetic included an annual comprehensive dilated eye and visual exam by an ophthalmologist or optometrist for all patients over the age of thirty. There was no documentation of such comprehensive dilated eye exams by medical clinic providers. Seventy-six percent of the patients (23) were given ophthalmology referrals; however, only 52% of the referrals (12) were completed. This means that 18 patients or 60% had no eye exam by medical provider, ophthalmologist, or optometrist in the medical center from 1 May 1994 to 30 April 1995. (See Table 3.)

While 43% of the records (13) documented podiatry referrals, 33% of the records (10) documented visits to a podiatrist. Since the ADA Standards of Medical Care did specify that foot exams should be done with every regular exam, medical providers only received credit for foot exams that they performed themselves and whose assessment addressed at least two of the following: skin condition, pulse/vascular status, and. neurological status. Twenty-three percent of the patients (7) received one foot exam from 1 May 1994 to 30 April 1995; 29% (2) of these received podiatry referrals, only one of which was completed. Twenty-three percent of the patients (7) received 2 to 3 foot exams

from their medical clinic providers; 57% (4) of these received podiatry referrals, three of which were completed. Of the 53% of patients (16) who did not have foot exams from their medical providers, only 44% (7) received a podiatry referral, six of which were followed through with a range of 2 to 5 visits. Based on the minimum of two visits per year, the medical clinic providers clearly did not perform the recommended number of foot exams for 53% of the patients (16). This number could increase depending on the number of required regular visits for each patient.

Table 3.

Ophthalmological^a and Podiatry Referrals and Exams^b

Ophthalmological Referrals and Exams	#	%
Referrals Initiated	23	(76%)
Referrals Completed	12	(40%)
Dilated Exams per MC Provider	0	(0%)
Total Patients Without Annual Dilated Eye Exam	1	(60%)

Table 3a.Podiatry Referrals and Exams.

Referrals and Exams	#	%
Referrals Initiated	13	(43%)
Referrals Completed	10	(33%)
Two Complete Foot Exams by MC Provider	7	(23%)
Total Patients Without Foot Exams	10	(33%)

^a includes visits to Optometry^b based upon total number of visits

The ADA Standards of Medical Care recommended an oral examination upon the initial visit of a diabetic patient. The ADA management plan for continuing care of the diabetic recommended assessment of adherence to all aspects of self care at each regular visit but makes no specific reference to an oral exam. Therefore, while reference to dental

status was noted in only one patient record, no assessment was made to the adherence of a dental standard of care.

Although an electrocardiogram (EKG) was recommended for all adult diabetic patients during their initial visits, ADA Standards of Medical Care did not specify EKGs for the continuing care of the diabetic patient. However, EKGs were deemed important by two panels of diabetic experts, therefore, the presence of an EKG performed between 1 May 1994 and 30 April 1995 was assessed. Since it could be considered cost-effective to defer a nonemergent EKG if one had been done recently, medical providers received credit for any EKG performed during the study year regardless of the site of origin. Based upon this criteria, nearly 47% of the diabetic patients (14) had documentation of an EKG accomplished or ordered.

Glucose Monitoring

The ADA (1988) had determined biochemical indices of metabolic control for the Type II diabetic with adjustments to be made for normal values of the laboratory used. Normal (top limits) for a fasting blood glucose was 115 mg/dl, acceptable was 140 mg/dl, and poor was >200 mg/dl (ADA, p. 25). The most recent serum glucose levels performed by the laboratory ranged from 60 to 461 mg/dl. Without factoring the number of visits, approximately 34.5% of the patients had acceptable blood glucose levels of less than 140 mg/dl; 27.6% had blood glucose levels of 140 to 200 mg/dl; 37.9% had blood glucose levels of 200 to 400 mg/dl.

For further analysis, the sample was divided into two groups: (See Table 4.) Group I consisted of 18 patients with 2 to 4 yearly visits to the medical clinic; Group II consisted of 11 patients with 5 to 11 yearly visits to the medical clinic. Utilizing the most

recent serum blood glucose level, 50% of the patients in Group I had glucose levels of less than 140 mg/dl; 33.3% had glucose levels of 140 to 200 mg/dl; 16.7% had glucose levels greater than 200 mg/dl. One patient's only glucose level was a Dextrose fingerstick of 120.

In Group II, 9% of the patients had serum blood glucose levels of less than 140 mg/dl; 27% had blood glucose levels of 140 to 200 mg/dl; and 64% had blood glucose levels of greater than 200 mg/dl.

A substantial difference was noted in the number of patients with acceptable glucose levels with Group I, the group with fewer yearly clinical visits, outnumbering the second group by 41%. A smaller difference of 6.3% was also noted in the mid-range (140 - 200 mg/dl) again favoring Group I. On the other hand, Group II had 47% more patients in the poor control range. More frequent visits did not result in better blood glucose control.

Utilizing the same groups of patients, a different picture evolved when the number of visits was related to the most recent hemoglobin A1C levels. (See Table 4a.) The laboratory at the medical center used the following values: < 6 excellent; 6 - 7 good; 7 - 8 fair; > 8 poor. Approximately 11.8% of Group I fell into the 6 - 7 control range; 23.5% into the 7 - 8 control range; 64.7% into the >8 control range. Two patients in this group had no recorded hemoglobin A1C levels in their medical records. No patients from Group II fell into the excellent or good categories. Eighteen point two percent (2) fell into the 7 - 8 control range and 81.8% (9) fell into the >8 control range. The hemoglobin A1C statistics from Group II were similar to those obtained in the blood glucose evaluation described above and came as no great surprise. There was an increase of almost 18% in the number

of poorly controlled diabetics using the hemoglobin A1C as a measurement. The hemoglobin A1C was a reflection of glucose control over a three month period and was a more reliable assessment tool. The results for Group I indicated the majority of patients had poor diabetes control similar to that of the patients in Group II. However, Group I still had higher percentages of patients with good and fair control, with a difference of 11.8% and 5.3% respectively. It also had 17.1% fewer patients with poor diabetes control.

Table 4.

Latest Serum Blood Glucose Levels Related to the Number of Yearly Visits.

Glucose levels	Group I (N=18)	Group II (N=11)
< 140 mg/dl	9 (50%)	1 (9%)
140 - 200 mg/dl	6 (33.3%)	3 (27%)
> 200 mg/dl	3 (16.7%)	7 (64%)

Table 4a.

Latest Hemoglobin A1C Levels Related to the Number of Yearly Visits.

A1C levels	Group I (N=17)	Group II (N=11)
< 6	0 (0%)	0 (0%)
6 - 7	2 (11.8%)	0 (0%)
7 - 8	4 (23.5%)	2 (18.2%)
>8	11 (64.7%)	9 (81.8%)

The frequency of blood glucose and glycohemoglobin measurements were also assessed. Sixteen patients (53%) of the patients had their blood sugar levels drawn or ordered 4 times or more during the year; the remaining 14 patients (47%) had their blood glucose levels drawn or ordered 1 to 3 times during the year. These totals did not include D-sticks performed in the Diabetic Education classes attended by the patients. These fig-

ures were examined further to determine if frequency of measurement of glucose levels affected the glucose control. (See Table 5.) Of the thirteen patients who had their glucose levels drawn 1 to 3 times during the year, 46% had glucose levels of < 140 mg/dl, 23% had levels of 140 to 200 mg/dl, and 31% had glucose levels of >200 mg/dl. One chart reflected a serum glucose ordered but not completed. Of the sixteen patients who had their blood drawn 4 times or more during the year, 25% had glucose levels of <140 mg/dl, 31% had levels of 140 to 200 mg/dl, and 44% had glucose levels > 200 mg/dl. The number of glucose levels measured did not ensure that the blood glucose would be within the acceptable range of less than 140 mg/dl for the diabetic patient.

The most recent documented glycohemoglobin levels ranged from 6.5 to 13.1 with one patient not tested. Twenty-five patients (83%) had hemoglobin A1C levels drawn 2 or more times during the year; three patients (10%) had levels drawn or ordered only once during the year. Two patients (7%) did not have a hemoglobin A1C drawn at all although orders were written for both patients.

These figures were also examined to determine if the frequency of hemoglobin A1Cs affected the serum glucose level. (See Table 5a.) The sample was divided into two groups. Group I consisted of three patients with hemoglobin A1Cs drawn once during the study year; Group II consisted of 25 patients with at least two hemoglobin A1Cs drawn during the study year. Based upon laboratory values of < 6 excellent, 6 - 7 good, 7 - 8 fair, >8 poor, hemoglobin A1C levels of all three patients in Group I fell into the >8 control range. Eight percent of Group II (2 patients) fell into the 6 - 7 control range, 24% (6) fell into the 7 - 8 control range, and the majority (68%) (17) fell into the >8 control range. Once again the frequency of laboratory studies (i.e. hemoglobin A1C levels) did not en-

sure good blood glucose control.

Table 5.

Latest Serum Blood Glucose Levels Related to Frequency of Laboratory Studies.

Glucose levels	Group I N=13)	Group II (N=16)
< 140 mg/dl	6 (46%)	4 (25%)
140 - 200 mg/dl	3 (23%)	5 (31%)
>200 mg/dl	4 (31%)	7 (44%)

Table 5a.

Latest Hemoglobin A1C Levels Related to Frequency of Laboratory Studies.

A1C levels	Group I (N=3)	Group II (N=25)
<6	0 (0%)	0 (0%)
6 - 7	0 (0%)	2 (8%)
7 - 8	0 (0%)	6 (24%)
>8	3 (100%)	17 (68%)

The ADA Standards of care recommended results of self-monitoring blood glucose (SMBG) should be assessed with each visit although frequency of SMBG depends upon the form of treatment and patient response to the treatment. This individualization made it difficult to evaluate according to the standard; however, documentation showed that SMBG was addressed in 28 patient records (93.3%) at least once during the study

year. No medical records contained reference to self urine glucose monitoring, an alternative used when the patient is unable or unwilling to perform SMBG testing or when the only goal is to avoid hyperglycemia.

General Care

Assessment of nutritional status and exercise regimen at regular visits was also part of the ADA recommendations however, compliance to the vague criteria of “regular visits” was difficult to assess. Data regarding the total number of assessments for these elements of care during the study year was not obtained. Based on yes/no criteria on the DQA checklist, 90% of the medical records had documentation of a nutritional assessment in at least one visit by the provider. Nearly 43% of the patients received a nutritional consult. Four patients received nutritional consults in March and April 1994 prior to the opening date of the study. Seventy percent of the patients had specific diets prescribed. Documentation for two of these diets was found on hospital discharge summaries; the remaining diets were prescribed by the nutritionist. One patient was misscheduled into the Nutritional class, chose to stay, and was prescribed an ADA diet by the nutritionist. Hence, for 10% of the patient charts reviewed, the medical providers failed to comply with the ADA standards for assessment of nutritional status. This number may be higher depending on the number of regular visits deemed appropriate for each patient.

Seventy-seven percent (23) of the medical records showed the provider had addressed exercise at least once during the study year. The remaining 23% of patients (7) had attended diabetic classes in which the basic principles of diet and exercise were addressed. Compliance to the standard on exercise was not met in at least 23% of the cases. Again, this number could be higher depending on the number of regular visits.

Twenty-nine of the patients in this study received referrals to the Diabetic Education classes sponsored by the medical clinic. The remaining one patient was given a referral shortly before this study began; the provider addressed this referral in the medical record after the study began. Ninety-six percent of these referrals were completed; one patient declined to attend the classes; one patient attended the class after the study deadline of 30 April 1995. It must be remembered that the master list of diabetic patients for this study was comprised of patients already enrolled in Diabetic Education classes. Data is not available to compare this information with the total number of diabetic patients seen in the medical clinic.

Assessment of Cardiovascular Risk Factors

Height, weight, and blood pressure were documented in all of the patients' medical records at least one time during the study year. Although height was not recorded as often, weight and blood pressure were recorded in every visit to the medical clinic.

Twenty-five medical records (83.3%) contained documentation of smoking assessment. If the provider did not address the issue of smoking, credit was still given if the smoking status was marked negative on the problem sheet in the front of the medical record. No distinction was made regarding which clinic or provider documented the smoking history.

Yearly Laboratory Tests

ADA Standards of Medical Care recommended that cholesterol, triglycerides, high density lipoproteins (HDL) and low density lipoproteins (LDL) be tested annually for all adults with abnormal lipid profiles and as needed to monitor treatment success for dyslipidemia. Laboratory studies, particularly the lipid profile, could be ordered by spe-

cialty areas as well as the medical clinic. Again, if the study was nonemergent and had been accomplished recently it would behoove the provider to defer the test until a later time; therefore, only the presence or absence of the lipid profile and serum creatinine levels were noted in this study. Twenty-five patients (83.3%) had their cholesterol, HDL, LDL, and triglycerides drawn or ordered at least once from 1 May 1994 to 30 April 1995.

The ADA Standards of Care recommended routine analysis be performed yearly. It went on to say that serum creatinine or urea nitrogen should be measured and glomerular filtration assessed if the albumin or protein levels secreted are abnormal. Sixty-six percent of the medical records showed documentation of a urinalysis or a 24-hr. protein done at least once from 1 May 1994 to 30 April 1995. Data was not obtained to determine what percent of the sample had renal complications. Ninety percent of the medical records (27) showed documentation of serum creatinine levels. One medical record had no documentation of any urine test being ordered or performed during the study year.

Adherence Ratings: Ten Specific ADA Standards and DQA Checklist

Adherence ratings were calculated for ten elements of care specifically addressed in the ADA Standards of Medical Care and for overall adherence to all elements of care listed on the DQA Checklist. The grading system used was based on the total grading scale devised by the two diabetic experts during their evaluation of the DQA Checklist prior to the pilot study. A score of 86% or higher was considered excellent adherence, 80 - 85% good adherence, 75 - 79% average adherence, 67 - 74% poor adherence, and 66% (or lower) very poor adherence. Specific elements of care addressed in the Standards of Care included ophthalmology referral, self-monitoring blood glucose, diet, exer-

cise, foot care, weight, B/P, smoking, and urine analysis. Serum blood glucose monitoring was included based on the minimum number of visits required (semiannual) with a serum blood glucose drawn for each visit. A maximum of 55 points was possible for the specific elements of care with a maximum of 110 points possible for overall adherence.

Table 6 shows the providers' adherence to the ten specific elements of care listed above. The range of points was 26 to 55 with a mean of 43 points. Thirty percent of the medical records rated excellent, 13% rated good, 17% rated average, 13% rated poor, and 27% rated very poor.

Table 6.

Providers' Adherence to Ten Specific Elements of Care Addressed in the ADA Standards of Medical Care.^a

Number of points	Number of records
55 - 47 (excellent)	9 (30%)
46 - 44 (good)	4 (13%)
43 - 41 (average)	5 (17%)
40 - 37 (poor)	4 (13%)
<36 (very poor)	8 (27%)

^a Specific elements of care included ophthalmology referral, self-monitoring blood glucose, serum blood glucose monitoring, diet, exercise, foot care, weight, B/P, smoking, and urine analysis.

Although all of the elements of care listed on the DQA Checklist were not specifically addressed in the ADA Standards of Care, all were deemed important areas of assessment for continuing care of the diabetic patient by diabetic experts both in the Wylie-Rosett study and this study. (The frequency of visits was not included in the overall evaluation because it was listed on the Demographic Information sheet.) The range of points for overall adherence to these important elements of diabetic assessment was 48 to 92 points with a mean of 73.9 points. No medical records obtained a rating of excellent. Ten percent of the records rated good, 10% rated average, 40% rated poor, and 40% rated very poor. Table 7 shows the providers' overall adherence to elements of care listed on the DQA Checklist.

Table 7.

Provider Adherence to the Diabetic Quality Assurance Checklist.

Number of points	Number of records
110 - 95 (excellent)	0 (0%)
94 - 88 (good)	3 (10%)
87 - 83 (average)	3 (10%)
82 - 74 (poor)	12 (40%)
< 76 (very poor)	12 (40%)

Demographic information in this study revealed a mean age of 64 years with 43% men (all former active duty), and 53% white. The mean years of diagnosis was 9.9 years; 40% of the patients had been diagnosed with diabetes mellitus five years or less. The majority of patients had visited the Medical Center an average of 10.7 yearly visits; almost half had frequented the Emergency Department. The mean number of visits to the medical clinic was 4.3 with the majority of patients seeing the same provider throughout the study year. The medical clinic providers did not perform comprehensive dilated eye exams and referred approximately three-fourths of the patients to Ophthalmology/Optometry, although not quite half of these referrals were completed. Providers did poorly in foot exams with only 23% adherence to standards of foot care. Dental status was addressed in one chart. Diabetic Education referrals were given to 29 patients with a 96% compliance rate. While a little over half of the patients had blood glucose levels

drawn four times or more, 83% of the patients had hemoglobin A1C levels drawn at least twice. Increased frequency of laboratory studies did not ensure good glucose control in either scenario. Based upon the most recent serum blood glucose test, half of the patients with less frequent visits revealed acceptable serum glucose levels. However, hemoglobin A1C levels revealed poor blood glucose control for the majority of patients regardless of the number of visits. Despite the number of patients with poorly controlled blood glucose, 93% of the patients reported that they performed self blood glucose checks at home. Self-urine glucose testing was not addressed by any medical clinic providers. Nutritional status and exercise were addressed in the majority of the medical records. Weight and blood pressure were documented at every medical clinic visit with smoking addressed in some fashion in 83% of the records. Lipid profiles were drawn in 83% of the patients, serum creatinine levels in 90% of the patients. The medical clinic providers met the yearly urine analysis standard in 63% of the patients.

Forty-three percent of the medical records received a good or excellent rating in adherence to the 10 specified ADA Standards. Overall adherence to the elements of care on the DQA Checklist resulted in only 10% of the charts receiving a good to excellent rating.

CHAPTER FIVE

This chapter provides a brief summary of the study and conclusions and recommendations drawn from the data presented in chapter four.

This quantitative study assessed the process of care involving the continuing treatment and education of patients with Type II diabetes mellitus. It utilized the Basic Assessment portion of the Diabetes Quality Assurance Checklist based upon the normative standards published by the American Diabetes Association. A chart review of 30 randomly selected medical records was performed resulting in the calculation of adherence to ten specific ADA Standards of Medical Care and overall adherence to the DQA Checklist. Separate calculations were a result of the comprehensive list of important elements of care found in the Checklist not routinely required by the ADA Standards. Grading was based upon individual points assigned to each element of care and a total grading scale devised by diabetic experts. Forty-three percent of the medical records rated good and excellent adherence to the ADA Standards of Care while only 10% of the records rated good adherence to the DQA Checklist. No medical records rated excellent adherence to the Checklist. This study did not investigate the reasons for low provider adherence to the Standards or the Checklist, however, some speculations regarding the results, problems encountered, and recommendations are included below.

Conclusions and recommendations

It was difficult rating adherence to all of the ADA Standards of Medical Care based on the yes/no criteria of the DQA Checklist. One problem that arose frequently when evaluating the elements of care was the ambiguity of certain portions of the Stan-

dards. This was due to the complexity of diabetes and the variations in treatments, patient responses, and complications from the disease. The Basic Assessment portion of the DQA Checklist served only as a basic screening tool. Evaluation of the providers' adherence to each individualized standard would have required in-depth research into each patient's health history. Although this would have allowed a more complete evaluation, it was beyond the scope of this study. Perhaps utilization of the High Risk Assessment and Intervention section of the DQA Checklist would allow a more in-depth investigation.

Physicians had a higher rate of adherence to specific elements of care addressed in the ADA Standards of Care versus the elements of care listed on the DQA Checklist. This may have been a reflection of the different levels of importance that providers placed on elements of care. A survey of the physicians' attitudes toward the ADA Standards would be helpful in determining the degree of influence if any. The physicians were not introduced to the DQA Checklist prior to this study and low adherence may have been a result of a lack of awareness of its contents. Reinforcing the physicians' knowledge of important elements of care for the diabetic patient and providing a copy of the DQA Checklist to each physician would help eliminate these potential problems. Interviews with the providers and/or patients after each visit may reveal inadequate documentation of the visit.

Some elements of care such as dental assessment and EKGs, although not specifically addressed in the continuing care section of the ADA Standards, were still deemed important in the ongoing assessment of diabetic patients. This led to some conflict regarding the fairness in scoring adherence. The result was the evaluation of the physicians' adherence in two ways, to ten specifically addressed standards and to the overall important

elements of diabetic continuing care. A comparison of the elements of care on the DQA Checklist with the standards used at the clinic would eliminate this conflict.

The number of medical clinic providers seen by each patient during the study year did not demonstrate a lack of comprehensive care as the result of frequent provider turn-overs as suggested in the introduction. However, the small number of providers and sample size make further research necessary before any conclusions could be drawn.

This quantitative study of the adherence of military providers to ADA Standards of Medical Care utilizing the Basic Assessment portion of the DQA Checklist touched only the tip of a very large iceberg. Further research is needed to provide conclusive answers regarding adherence to these Standards.

APPENDICES

Appendix A

STANDARDS OF MEDICAL CARE FOR PATIENTS WITH DIABETES MELLITUS

CONTINUING CARE-

Continuing care is essential in the management of every patient with diabetes. At each visit, the patient's progress in achieving treatment goals should be evaluated by the health-care team, and problems that have occurred should be reviewed. If goals are not being met, the management plan needs to be revised and/or the goals need to be reassessed.

Visit frequency

The frequency of patient visits depends on the type of diabetes, the blood glucose goals and the degree to which they are achieved, changes in the treatment regimen, and presence of complications of diabetes or other medical conditions.

Patients initiating insulin therapy or having a major change in their insulin program may need to be in contact with their

care provider as often as daily until glucose control is achieved, the risk of hypoglycemia is low, and the patient is competent and comfortable implementing the treatment plan. Some patients may require hospitalization for initiation or change of therapy.

Patients beginning treatment by diet or oral glucose-lowering agents may need to be contacted as often as weekly until reasonable glucose control is achieved and the patient is competent to conduct

the treatment program. Regular visits should be scheduled for insulin-treated patients at least quarterly and for other patients quarterly or semi-annually, depending on achievement of treatment goals. More frequent contact also may be required if the patient is undergoing intensive insulin ther-

apy, not meeting glycemic or blood pressure goals, or has evidence of progression in microvascular or macrovascular complications. Patients must be taught to recognize problems with their glucose control as indicated by their records of self-monitoring of blood glucose and to promptly report concerns to the health-care team to clarify and strengthen their self-management skills. They also should be taught to recognize early signs and symptoms of acute and chronic complications and to report these immediately. Severe hypoglycemic reactions requiring the assistance of another person must be reported as soon as possible.

Medical history

An interim history should be obtained at each visit and include: 1) frequency, causes, and severity of hypo-

glycemia or hyperglycemia; 2) results of self-monitoring; 3) adjustments by the patient of the therapeutic regimen; 4) problems with adherence; 5) symptoms suggesting development of the complications of diabetes; 6) other medical illnesses; 7) current medications; 8) psychosocial issues; and 9) lifestyle changes.

Physical exam

At every regular visit, height (until maturity), weight, and blood pressure should be measured. Sexual maturation should be evaluated periodically in peripubertal patients. Portions of the physical examination that were found to be abnormal on previous visits should be repeated. The fundi should be examined at regular visits (preferably with dilation). If retinopathy is detected for the first time or has progressed or if there are visual symptoms, the patient should be referred to an ophthalmologist or optometrist for a prompt, complete dilated eye

and visual examination. The feet should be examined at every regular visit for assessment of vascular status, skin condition, and sensation. If there is evidence of significant ischemia, loss of protective sensation, deformity, ulceration, or infection, the patient should be referred to the relevant specialist for appropriate testing, treatment, or intensive education as indicated. The physical examination should also be extended to include areas indicated by the interim history.

Comprehensive dilated eye and visual examinations should be performed annually by an ophthalmologist or optometrist for all patients age 12 and over who have had diabetes for 5 years, all patients over the age of 30, and any patient with visual symptoms and/or abnormalities.

Laboratory

A glycohemoglobin determination should be performed at least quarterly in all insulin-treated patients and

as frequently as necessary to assess achievement of glycemic goals in non-insulin treated patients. A fasting plasma glucose test may be useful to judge glycemic control in NIDDM patients. The value obtained from a plasma glucose test also may be useful for comparison with the value obtained simultaneously by the patient using his/her own monitoring systems.

Adults who have abnormal lipid profiles should be tested annually for total cholesterol, fasting triglycerides, HDL-cholesterol, and LDL-cholesterol. If treatment is instituted for dyslipidemia, the appropriate laboratory measurement should be repeated as needed to monitor therapy. If all values are within acceptable limits, the clinician may consider obtaining this lipid profile less frequently.

A lipid profile should be performed on children older than 2 years, after diagnosis of diabetes and when glucose control

has been established. Borderline or abnormal values should be repeated for confirmation. If values fall within accepted risk levels, assessment should be repeated every 5 years. Abnormal values requiring institution of therapy should be repeated following the National Cholesterol Education Program recommendations.

Routine urinalysis should be performed yearly in adults. In postpubertal patients who have had diabetes for 5 years, a timed urine collection specimen (e.g., 24 h or overnight) should be tested for the pres-

ence of microalbumin or the albumin/creatinine ratio should be measured yearly. If abnormal albumin or protein excretion is detected, serum creatinine or urea nitrogen concentrations should be measured and glomerular filtration assessed.

Management plan

The management plan should be reviewed at each regular visit to determine progress in meeting goals and to identify problems. This review should include the control of blood glucose levels, assessment of complications, control of blood pres-

sure, control of dyslipidemia, nutrition assessment, frequency of hypoglycemia, adherence to all aspects of self-care, evaluation of the exercise regimen, follow-up of referrals, and psychosocial adjustment. In addition, knowledge of diabetes and self-management skills should be reassessed at least annually. Continuing education should be provided or encouraged

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Appendix B

DIABETES QUALITY ASSURANCE CHECKLIST

Basic Assessment			
Chart #	Code #		
Today's date	Beginning date	Ending	
Date			
Patient's initials	Date of last visit		
Referrals made in past year			
Dental	Y	N	(5 pts)
Ophthalmology	Y	N	(10 pts)
EKG/Cardiology	Y	N	(3 pts)
Monitoring/Blood Glucose Evaluation			
Over the past year, blood glucose measured			
1- 3 times	Y	N	(5 pts)
4 + times	Y	N	(10 pts)
Glycohemoglobin measured			
1 time	Y	N	(5 pts)
2 + times	Y	N	(10 pts)
Home glucose monitoring			
urine/unspecified	Y	N	(6 pts)
blood	Y	N	(10 pts)
General Care			
Diet intervention specified	Y	N	(4 pts)
Nutritionist (RD) consulted	Y	N	(6 pts)
Nutrition noted by other staff	Y	N	(2 pts)
Prescription for exercise/ physical activity	Y	N	(4 pts)
Provided/ referred for diabetes education	Y	N	(4 pts)
Foot Care			
Foot exam must consist of at least 2 of the following: skin condition; pulse/vascular; neurological			
Foot exam			
1 time Per year	Y	N	(5 pts)
2 + times per year	Y	N	(10 pts)
Podiatry referral	Y	N	(5 pts)
Assessment of Cardiovascular Risk Factors			
weight measured	Y	N	(2 pts)
height measured	Y	N	(2 pts)
blood pressure measured	Y	N	(2 pts)
assessed smoking	Y	N	(3 pts)

Laboratory Tests

cholesterol	Y	N	(2 pts)
HDL cholesterol	Y	N	(2 pts)
triglycerides	Y	N	(2 pts)
serum creatinine	Y	N	(2 pts)
urinaryprotein	Y	N	(2 pts)
LDL	Y	N	(2 pts)

Appendix C

DEMOGRAPHIC INFORMATION FOR ENROLLED SAMPLE

Sex _____

Race _____

Age _____

Year of Diagnosis _____ Numbers of years diagnosed _____

Number of providers at the clinic during study year _____

Number of providers per patient during study year _____

Number of visits during study year:

at Malcolm Grow Internal Medicine Clinic _____

at MG emergency room department _____

at other health care clinics _____

at other emergency room departments _____

Last glucose level obtained _____

Last glycosylated hemoglobin level obtained _____

Appendix D

ADA STANDARDS: THE NORM?

ITEM: Instruction sheet

PURPOSE: assess validation of research tool

Enclosed are copies of the standards of care published by the American Diabetes Association entitled Standards of Medical Care for Patients With Diabetes Mellitus, the Diabetes Quality Assurance (DQA) Checklist, evaluation sheets for the relevance of elements, assigned numerical value, and total grading scale, and an addressed return envelope. The individual elements on the DQA checklist were selected to represent the ADA standards and other nonstandard items deemed important to the care of the diabetic patient.

Utilizing the evaluation sheet marked relevance of element, please evaluate the individual elements found on the DQA Checklist and rate the relevance of each element utilizing the scale of 4 to 1 provided. The number four represents an element which is very relevant; number three represents an element which is relevant; number two represents an element which is somewhat relevant; number one represents an element which is not relevant. Circle the number representing your choice.

Utilizing the evaluation sheet marked relevance of assigned numerical value, please evaluate the numerical value assigned to each individual element and rate the relevance of each numerical value utilizing the scale of 4 to 1 provided. The number four represents a numerical value which is very relevant; number three represents a numerical value which is relevant; number two represents a numerical value which is somewhat relevant; number one represents a numerical value which is not relevant. Circle the number representing your choice.

Utilizing your expertise in diabetes mellitus, please devise a total grading scale for the one hundred points possible to denote excellent, good, average, poor and very poor compliance with the elements in the checklist. Please include this scale on the page entitled total grading scale. Additional comments and suggestions may be included on this page.

Upon completion of your assessment, please mail the evaluation sheets in the stamped envelope provided. Tabulation of the results will begin the 1st. of September, 1995. Please direct any questions regarding this evaluation to Captain Deborah Flagg. I may be reached at (301) 599-9364 or (301) 295-1991. My mailing address is 4010-1 Beech Lane, Andrews Air Force Base, MD, 20335.

Thank you for your time and effort. Your support is greatly appreciated. If you are interested, I would be happy to provide you with a copy of the final tool or information regarding the study.

Captain Deborah Flagg
Uniformed Services University of the Health Sciences
Graduate School of Nursing student

Appendix E

DIABETES QUALITY ASSURANCE CHECKLIST: Relevance of element

INSTRUCTIONS: Please evaluate the individual elements and rate the relevance of each element utilizing the scale of 4 to 1 provided below. The number four represents an element which is very relevant; number three represents an element which is relevant; number two represents an element which is somewhat relevant; number one represents an element which is not relevant. Circle the number representing your choice.

<u>Elements</u>	<u>Relevance of element</u>			
<u>Referrals made in past year</u>				
Dental	4	3	2	1
Ophthalmology	4	3	2	1
EKG/Cardiology	4	3	2	1
<u>Monitoring/Blood Glucose Evaluation</u>				
Over the past year, blood glucose measured				
1 - 3 times	4	3	2	1
4 + times	4	3	2	1
Glycohemoglobin measured				
1 time	4	3	2	1
2 + times	4	3	2	1
Home glucose monitoring				
urine/unspecified	4	3	2	1
blood	4	3	2	1
<u>General Care</u>				
Diet intervention specified	4	3	2	1
Nutritionist (RD) consulted	4	3	2	1
Nutrition noted by other staff	4	3	2	1
Prescription for exercise/ physical activity	4	3	2	1
Provided/ referred for diabetes education	4	3	2	1
<u>Foot Care</u>				
Foot exam must consist of at least 2 of the following: skin condition; pulse/vascular; neurological				
<u>Foot exam</u>				
1 time per year	4	3	2	1
2 + times per year	4	3	2	1
Podiatric referral	4	3	2	1
<u>Assessment of Cardiovascular Risk Factors</u>				
weight measured	4	3	2	1
height measured	4	3	2	1
blood pressure measured	4	3	2	1
assessed smoking	4	3	2	1

DIABETES QUALITY ASSURANCE CHECKLIST: Relevance of element (cont)

Laboratory Tests

cholesterol	4	3	2	1
HDL cholesterol	4	3	2	1
triglycerides	4	3	2	1
serum creatinine	4	3	2	1
urinary protein	4	3	2	1

Appendix F

DIABETES QUALITY ASSURANCE CHECKLIST: Relevance of assigned numerical value

INSTRUCTIONS: Please evaluate the numerical value assigned to each individual element and rate the relevance of each numerical values utilizing the scale of 4 to 1 provided below. The number four represents a numerical value which is very relevant; number three represents a numerical value which is relevant; number two represents a numerical value which is somewhat relevant; number one represents a numerical value which is not relevant. Circle the number representing your choice.

For example, dental referral is assigned a value of five points with a maximum of ten points possible. If the number of points assigned to dental referral is very appropriate in reflecting the importance of the element circle the number four.

Dental	(5 pts)	4	3	2	1
--------	---------	---	---	---	---

ElementsRelevance of assigned numerical valueReferrals made in past year

Dental	(5 pts)	4	3	2	1
Ophthalmology	(10 pts)	4	3	2	1
EKG/Cardiology	(3 pts)	4	3	2	1

Monitoring/Blood Glucose Evaluation

Over the past year, blood glucose measured

1 - 3 times	(5 pts)	4	3	2	1
4 + times	(10 pts)	4	3	2	1

Glycohemoglobin measured

1 time	(5 pts)	4	3	2	1
2 + times	(10 pts)	4	3	2	1

Home glucose monitoring

urine/unspecified	(6 pts)	4	3	2	1
blood	(10 pts)	4	3	2	1

DIABETES QUALITY ASSURANCE CHECKLIST: Relevance of assigned numerical value (cont)

General Care

Diet intervention specified	(4 pts)	4	3	2	1
Nutritionist (RD) consulted	(6 pts)	4	3	2	1
Nutrition noted by other staff	(2 pts)	4	3	2	1
Prescription for exercise/ physical activity	(4 pts)	4	3	2	1
Provided/ referred for diabetes education	(4 pts)	4	3	2	1

Foot Care

Foot exam must consist of at least 2 of the
following: skin condition; pulse/vascular;
neurological

Foot exam

1 time per year	(5 pts)	4	3	2	1
2 + times per year	(10 pts)	4	3	2	1
Podiatry referral	(5 pts)	4	3	2	1

Assessment of Cardiovascular Risk Factors

weight measured	(2 pts)	4	3	2	1
height measured	(2 pts)	4	3	2	1
blood pressure measured	(2 pts)	4	3	2	1
assessed smoking	(3 pts)	4	3	2	1

Laboratory Tests

cholesterol	(2 pts)	4	3	2	1
HDL cholesterol	(2 pts)	4	3	2	1
triglycerides	(2 pts)	4	3	2	1
serum creatinine	(2 pts)	4	3	2	1
urinary protein	(2 pts)	4	3	2	1

Appendix G

TOTAL GRADING SCALE

INSTRUCTIONS: Please devise a total grading scale for the one hundred points possible to denote excellent, good, average, poor, and very poor compliance with the elements in the checklist.

Excellent = _____ points

Good = _____ points

Average = _____ points

Poor = _____ points

Very Poor = _____ points

ADDITIONAL COMMENTS AND SUGGESTIONS:

Appendix H

EVALUATORS' SCORES FOR THE RELEVANCE OF ELEMENTS OF CARE AND
NUMERICAL VALUES

<u>ELEMENTS OF CARE:</u>	<u>ELEMENT</u>		<u>NUM. VALUES</u>	
	<u>rater 1</u>	<u>rater 2</u>	<u>rater 1</u>	<u>rater 2</u>
<u>Referrals made in past year</u>				
dental	3	2	3	2
ophthalmology	4	4	4	4
EKG	3	3	2	3
<u>Blood glucose evaluation</u>				
1-3 times/yr.	4	3	4	2
4+ times/yr.	4	4	4	4
glycohemoglobin 1 time/yr.	4	3	4	2
glycohemoglobin 2+ times/yr.	4	4	4	4
home glucose monitoring				
urine	4	2	4	2
blood	4	4	4	4
<u>General care</u>				
diet intervention	4	4	4	4
nutritionist consulted	4	4	4	4
nutrition noted	4	4	4	4
exercise/activity	4	4	4	4
diabetes education	4	4	4	4
<u>Foot exam</u>				
one time/yr.	4	2	2	4
two + times/yr.	4	3	3	4
Podiatry referral	3	3	3	4
<u>CV risk factors</u>				
weight	4	3	2	2
height	4	2	2	2
B/P	4	3	4	2
smoking assessed	3	4	4	4
<u>Laboratory tests</u>				
cholesterol	3	3	3	4
HDL	3	3	3	4
triglycerides	3	3	3	4
serum creatinine	3	3	3	4
urinary protein	3	3	3	4

Appendix I

EVALUATORS' SCORES FOR TOTAL GRADING SCALE

	<u>rater 1</u>	<u>rater 2</u>	<u>combined</u>
excellent	85	88	86
good	80	80	80
average	75	75	75
poor	70	65	67
very poor	60	55	57

EVALUATORS' SUGGESTIONS:

Assign adults over age 50 higher points.

Increase point value for weight (3 pts), height (3 pts), B/P (4 pts).

Increase the weight assigned to general care and include elements (2+) that pertain specifically to patient compliance. The key issue being that patient compliance would be documented in a meaningful and supportive way.

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